Supreme Court, U.S.
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No. 09-_____

IN THE

Supreme Court of the United States

ORTHO BIOTECH PRODUCTS, L.P.,

Petitioner,

v.

UNITED STATES EX REL.
MARK EUGENE DUXBURY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a federal court lacks subject-matter jurisdiction over a *qui tam* suit under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, that repeats publicly disclosed allegations from prior litigation, where the FCA relator did not provide the government with information on the suit's allegations before the public disclosure.

2. Whether an FCA relator, alleging that the defendant induced a third party to submit false or fraudulent claims, can satisfy Rule 9(b) of the Federal Rules of Civil Procedure without identifying a single false or fraudulent claim, but merely by alleging facts sufficient "to strengthen the inference of fraud beyond possibility."

PARTIES TO THE PROCEEDING AND RULE 29.6 DISCLOSURE STATEMENT

The following list provides the names of all parties to the proceedings below.

The Petitioner, Ortho Biotech Products, L.P. ("OBP"), was the defendant-appellee in the appeal below. OBP is a New Jersey corporation and subsidiary of parent corporation Johnson & Johnson, also a New Jersey corporation. No publicly held corporation other than Johnson & Johnson owns 10% or more of OBP's stock.

The Respondent, Relator Mark Eugene Duxbury, was a plaintiff-appellee in the appeal below. Duxbury's counsel has moved in the district court to substitute Duxbury's spouse for Relator Duxbury, who died after the court of appeals issued its decision.

The only other party to the appeal below was Relator Dean McClellan, a co-plaintiff-appellee with Relator Duxbury in that appeal. The court of appeals affirmed the dismissal of all of Relator McClellan's claims, and none of his claims are at issue in this petition.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Ortho Biotech Products, L.P. ("OBP") respectfully submits this petition for a writ of certiorari to review the decision of the United States Court of Appeals for the First Circuit. This petition presents the Court with an opportunity to eliminate conflicts among the federal circuits as to (1) the "original source" exception to the "public disclosure bar" of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, and (2) the application of Rule 9(b) of the Federal Rules of Civil Procedure to allegations of FCA violations.

On the "original source" issue, the First Circuit held—in accord with the Fourth and Eighth Circuits, but contrary to the Second, Sixth, Ninth, and D.C. Circuits—that an "original source" need not inform the government about an alleged fraud before someone else independently discloses the same allegations. As the United States explained in the amicus brief it filed in this case, "proper application of the FCA's public disclosure bar is critical to enforcement of that statute." Brief for the United States as Amicus Curiae, No. 08-1409, at 3 (Aug. 28, 2008). Because the First Circuit rejected the United States' view on the FCA's "proper application," and because the First Circuit's approach permits relators who are not true whistleblowers to qualify as an original source, the conflict on the "original source" question merits further review.

On Rule 9(b), the First Circuit held that an FCA relator is entitled to a "more flexible standard" that requires only the pleading of facts that "strengthen the inference of fraud beyond possibility." Pet. App.

33a, 38a. That rule is no more demanding than the Rule 8 standard this Court applied in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and is contrary to decisions of the Sixth, Eighth, and Eleventh Circuits that have rejected relaxing Rule 9(b) based on a relator's asserted lack of access to necessary information. Because the First Circuit's holding prevents Rule 9(b) in the context of the FCA from achieving its purpose of reducing the number of meritless and costly suits, the Rule 9(b) question also warrants this Court's review.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a) is reported at 579 F.3d 13. The decision of the district court (Pet. App. 44a) is reported at 551 F. Supp. 2d 100.

JURISDICTION

The judgment of the court of appeals was entered on August 12, 2009. Pet. App. 2a. A petition for rehearing en banc was denied on September 4, 2009. *Id.* at 79a-80a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS AND FEDERAL RULES INVOLVED

The provisions of the False Claims Act and Federal Rules of Civil Procedure involved are, in relevant part, as follows:

False Claims Act Provisions

31 U.S.C. § 3729(a)(1)

> [A]ny person who –
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;[1]
>
> . . . .
>
> is liable to the United States Government for a civil penalty . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

---

[1] Section 4(a) of the Fraud Enforcement And Recovery Act Of 2009, Pub. L. No. 111-21, 123 Stat. 1617, 1621-23 (May 20, 2009), amended 31 U.S.C. § 3729(a)(2) (1986), which made liable for an FCA violation anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." According to the Act,. the amended version "shall . . . apply to all claims . . . that are pending on or after [June 7, 2008]." *See* PL 111-21, at 1625. This petition refers to the new provision, although for purposes of this petition nothing turns on the changes in the provision's language because, among other things, the relator has failed to plead with particularity any false claims or any false records or statements allegedly linked to such claims.

31 U.S.C. § 3730(b)

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. . . .

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. . . .

. . . .

(4) Before the expiration of the 60-day period or any extensions [thereto] . . . the Government shall – (A) proceed with the action . . . or (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action. . . .

31 U.S.C. § 3730(e)(4) ("Public Disclosure Bar")

(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless . . . the person bringing the action is an original source of the information.

(B) ["Original Source" Provision:] For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

Federal Rules of Civil Procedure Provisions

Fed. R. Civ. P. 8(a): "**Claim for Relief.** A pleading that states a claim for relief must contain: . . . (2) a short and plain statement of the claim showing that the pleader is entitled to relief . . . ."

Fed. R. Civ. P. 9(b): "**Fraud or Mistake; Conditions of Mind.** In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."

STATEMENT OF THE CASE

1. a. The False Claims Act ("FCA") prohibits (among other things) knowingly submitting, or causing a third party to submit, to the government a "false or fraudulent claim" for payment, or knowingly using a "false record or statement" linked to such a claim. 31 U.S.C. § 3729(a)(1)(A)-(B). It contains "whistleblower" provisions that allow private citizens to sue on the government's behalf as "relators," *see id.* § 3730(b), through so-called "*qui tam*" suits. An FCA relator must initially file a complaint under seal and serve it on the government with a "written disclosure of substantially all material evidence and

information the person possesses." *Id.* § 3730(b)(2). The government then has at least sixty days to decide whether or not to intervene and take over the suit. *Id.* § 3730(b)(2), (4).

The FCA's "public disclosure bar" helps to ensure that only genuine "whistleblowers" become FCA relators. It precludes federal courts from exercising jurisdiction over any FCA suit that is "based upon" allegations that have already been publicly disclosed (in ways specified by the Act), unless the relator is an "original source." *Id.* § 3730(e)(4)(A). An "original source" must, first, have "direct and independent knowledge of the information on which the allegations are based"; and, second, have "voluntarily provided the information to the Government before filing an action . . . ." *Id.* § 3730(e)(4)(B).

1. b. Rule 9(b) requires that plaintiffs alleging fraud—including FCA relators—"must state with particularity" the "circumstances constituting fraud." This "particularity" requirement supplements Rule 8, which requires all plaintiffs to plead a "plausible," and not merely "possib[le]," right to relief. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949-50, 1954 (2009) (discussing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)). In pleading the "circumstances constituting fraud," a plaintiff must specify "matters such as the time, place, and contents of the false representations . . . as well as the identity of the person making the misrepresentation . . . ." 5A Charles Alan Wright and Arthur R. Miller, *Federal Practice and Procedure* § 1297 (3d ed. 2009). *See also, e.g., United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008); *United States ex rel. Rafizadeh v. Continental Common, Inc.*, 553 F.3d 869, 873 (5th Cir. 2008);

United States ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 518 (6th Cir. 2009); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006).

A plaintiff must allege specifics as to all of a fraud's legal elements other than mens rea, which Rule 9(b) exempts from heightened pleading. *See, e.g., United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 505 (6th Cir. 2008) (Rule 9(b) requires specifics about all "elements" other than "state of mind"). Essential to FCA fraud, and the focus of this petition, is "a false or fraudulent claim" for payment, *see* 31 U.S.C. § 3729(a)(1)(A)-(B), as well as, under § 3729(a)(1)(B), a "false record or statement" linked to such a claim.

Rule 9(b)'s "particularity" requirement serves important purposes. It helps to ensure that allegations are detailed enough to "enable the defendant to respond specifically and quickly to the potentially damaging allegations." *Joshi*, 441 F.3d at 556 (internal quotation marks and citations omitted). It also protects defendants from harassing "strike suits" and "fishing expeditions," which impose upon courts, parties, and society "enormous social and economic costs." *See Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001); *see also, e.g.*, John T. Boese, *Civil False Claims and Qui Tam Actions* § 5.04, at 5-45 – 5-47 (3d ed. 2009) ("Boese").

2. Petitioner Ortho Biotech Products, L.P. ("OBP") markets and distributes Procrit® ("Procrit"). Procrit treats anemia caused by chemotherapy, chronic kidney disease, HIV infection, and blood loss from certain types of surgery. Pet. App. 5a. Respondent Duxbury worked for OBP from 1992

until July 1998. *Id.* In November 2003, over five years after leaving OBP, and after a highly publicized, multi-district lawsuit alleged "AWP" fraud by various drug companies, including OBP, *see In re Pharm. Indus. Avg. Wholesale Price Litig.*, No. 01-12257-PBS, MDL No. 1456 (D. Mass.) ("AWP MDL"), Duxbury initiated this FCA lawsuit, Pet. App. 5a-6a, using counsel that had filed the AWP MDL's Master Consolidated Class Action Complaint. Duxbury's original complaint alleged the very same "kickback" fraud scheme already publicized by the AWP MDL. *Id.* at 15a, 59a.

In October 2006, after the government declined to intervene, Duxbury amended his complaint. The Amended Complaint added a new relator, Dean McClellan, and pleaded three counts, one of which (Count II) basically repeated the AWP allegations from the Original Complaint. *See* Pet. App. 10a-11a. That count was later voluntarily dismissed. *Id.* at 10a n.5. The two remaining counts alleged as follows: Count I alleged that OBP provided unlawful "kickbacks" to healthcare providers ("Providers"); Count III alleged that OBP promoted the use of "off-label" doses of Procrit to Providers. *Id.* at 11a. Both counts alleged that OBP caused third parties, the Providers, to submit false claims to Medicare. *See id.* No allegation asserted that OBP itself submitted any false claims. *Id.* at 34a.

This petition concerns Duxbury's "kickback" claims, which are the only claims remaining after the court of appeals decision. These claims rehash allegations that had been publicly disclosed in the AWP MDL. Duxbury conceded on appeal that his "kickback" claims were "based upon" the AWP MDL complaint. Pet. App. 15a. He also conceded that he

had not informed the government of his "kickback" allegations before they were disclosed years earlier in the AWP MDL. *Id.* at 16a.

The Amended Complaint alleges that "Relator Duxbury has specific knowledge that approximately 80 percent of Procrit sales that he generated were submitted by his accounts as false or fraudulent claims for Medicare reimbursement." Pet. App. 95a (Am. Compl. ¶ 211). The Amended Complaint, however, does not identify a single false claim. Pet. App. 36a. It does not allege any date of a false-claim submission or reimbursement, the actual content of any false claim, the amount requested in any false claim, or anything else that would effectively identify a false claim. *See id.* at 85a-106a (Am. Compl. ¶¶ 91-130, 211, 211a-h, 226-47).

3. The district court dismissed Duxbury's Amended Complaint. Pet. App. 78a. With respect to Duxbury's kickback claims, it first ruled that they survived the FCA's "public disclosure" bar. While recognizing that the kickback claims were "based upon" the previously disclosed AWP MDL, the court determined that Duxbury qualified as an "original source" for the period of his employment at OBP (1992-1998). *See* Pet. App. 59a, 61a. The court concluded that it was immaterial that Duxbury had not brought the alleged "kickback" fraud to the government's attention before the AWP MDL disclosed it. *See id.* at 60a. In the court's view, the relator had direct and independent knowledge of fraud and did not need to inform the government of the alleged fraud before filing suit. *See id.*

The district court next held that Duxbury's "kickback" claims did not satisfy the heightened

pleading standard of Rule 9(b). Pet. App. 77a. Relying on *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004), and *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720 (1st Cir. 2007), the district court held that "[a]lthough Duxbury identifies providers and approximate amounts of free samples, discounts, 'off-invoice' rebates, or educational grants, he fails to identify a single false claim consequently filed by . . . providers." Pet. App. 75a. The court observed that even the most specific of Duxbury's allegations "fail[ed] to provide even one (much less 'some') of the specifics required by *Karvelas* for 'at least some of the claims,' *viz.*, the 'dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based upon those practices.'" *Id.* at 75a-76a (quoting *Karvelas*, 360 F.3d at 232-33)).

The district court acknowledged that, under First Circuit precedent, Rule 9(b) allows some "flexibility" where "the complaint as a whole is sufficiently particular to pass muster . . . although some questions remain unanswered." Pet. App. 74a. "[E]ven giving Duxbury the benefit of such flexibility," however, the court ruled that "the allegations are inadequate." *Id.* at 75a (internal quotation marks and citation omitted).

Although Duxbury had protested that he could not "identify all the false claims submitted . . . because the claims 'were submitted to

Providers with most of whom Relator has no dealings, and the records of the false claims are not within Relator's control,'" the district court observed that "this is precisely the point of requiring relators to identify particular claims" under Rule 9(b). Pet. App. 76a (quoting Am. Compl. ¶ 232, Pet. App. 102a). Because a "court is not permitted to surmise that false claims 'must have' occurred as a result of defendant's conduct," the court dismissed Duxbury's "kickback" claims pursuant to Rule 9(b). Pet. App. 76a-78a.

4. The First Circuit reversed the district court's decision dismissing Duxbury's "kickback" claims. Pet. App. 43a. The court of appeals agreed with the district court that the public disclosure bar did not preclude Duxbury's suit, because he qualified as an "original source" for the "kickback" claims. The court held that it sufficed for Duxbury to inform the government of his allegations before filing suit, notwithstanding his failure to do so before those allegations were publicly disclosed. *Id.* at 30a. The court recognized that its holding conflicts with decisions in four other circuits and with the position of the United States, which filed a brief as amicus curiae supporting OBP's contention that Duxbury did not qualify as an "original source." *Id.* at 16a-17a (citing *United States ex rel. Dick v. Long Island Lighting Co.*, 912 F.2d 13 (2d Cir. 1990); *United States ex rel. McKenzie v. Bellsouth Telecomms., Inc.*, 123 F.3d 935 (6th Cir. 1997); *United States ex rel. Wang v. FMC Corp.*, 975 F.2d 1412 (9th Cir. 1992); *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675 (D.C. Cir. 1997)); *see also* Brief for the United States as Amicus Curiae,

No. 08-1409, at 21-24 (Aug. 28, 2008) ("United States Brief").

Observing that "[b]y its terms, the 'original source' exception only requires the relator to 'provide[] the information to the Government before filing an action under this section which is based on the information," the First Circuit concluded that "the plain terms of § 3730(e)(4)(B) begin and end the matter." Pet. App. 18a (quoting 31 U.S.C. § 3730(e)(4)(B)). The court rejected the government's reliance on the plain meaning of the term "original source"—"[t]he originator or primary agent of an act, circumstance, or result"—because "the statute *defines* the term at § 3730(e)(4)(B)." Pet. App. 18a-19a (quoting *Black's Law Dictionary* 1522 (9th ed. 2009)). The court also found that the relator had direct and independent knowledge of the allegations even though they were based upon allegations previously disclosed by someone else and the relator could not even identify a single false claim.

The First Circuit further reasoned—in direct conflict with at least the D.C. and 6th Circuits—that the structure and history of Section 3730(e)(4)(B) supported its position. Pet. App. 22a-30a. The court explained that the statute's structure "mitigates" concerns about permitting relators who are not true whistleblowers to be rewarded. *Id.* at 22a. The court noted that "the 'first-to-file' rule *already* provides potential relators significant incentive not to sit on the sidelines." *Id.* at 22a.

The First Circuit also asserted that this Court's decision in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007), "substantially undercuts" the alternative view presented by the

D.C. and Sixth Circuits. Pet. App. 22a. Citing *Rockwell*'s holding that the term "information" in Sections 3730(e)(4)(A) and 3730(e)(4)(B) "refers to the 'information underlying the allegations of the relator's action,' not the information underlying the public disclosure," the First Circuit explained that "*Rockwell* clarifies that the information that the original source has 'direct and independent knowledge' of does not have to be the same as the information upon which the public disclosure is based." *Id.* at 23a-24a (citation omitted). "[A]s a result of that clarification," the First Circuit continued, "*Rockwell* strongly suggests that situations can arise where the information upon which the public disclosure is based may be unavailable (such as a reporter protecting a source) or be of little value (if based on rumors), while a relator may have different information of the publicly disclosed fraud (such as eye-witness testimony, documents, etc.) of great significance." *Id.* at 24a. The court concluded that requiring a relator to inform the government of his information before a public disclosure "has the potential to bar productive suits." *Id.* at 25a.

As for history, the First Circuit observed that Congress amended the FCA in 1986 to "encourage more private enforcement suits." Pet. App. 26a (internal quotation marks omitted). All of these factors, the court concluded, supported its holding "that § 3730(e)(4)(B) only requires that a relator provide his or her information prior to the filing of the qui tam suit." *Id.* at 30a.

The First Circuit then turned to Rule 9(b). The court acknowledged that "Duxbury does not identify specific [false] claims," Pet. App. 36a, but concluded

that it sufficed that he alleged "factual . . . evidence to strengthen the inference of fraud beyond possibility," *id.* at 33a (quoting *Rost*, 507 F.3d at 733). The court explained that this "more flexible standard," *id.* at 35a (internal quotation marks and citation omitted), is appropriate for *qui tam* cases in which the defendant is alleged to have "induced *third parties*" to file false claims with the government," *id.* at 32a-33a.

Under the "more flexible [Rule 9(b)] standard," the court held that Duxbury's allegations established the requisite "inference of fraud." The court held that a few of the "kickback" paragraphs in the complaint satisfied Rule 9(b) because, it claimed, the paragraphs sufficiently addressed "the medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves," so as to support an inference that the commission of fraud was more than a "possibility." *Id.* at 36a, 38a.

5. OBP filed a petition for rehearing en banc, which the First Circuit denied on September 4, 2009. Pet. App. 79a-80a.

REASONS FOR GRANTING THE WRIT

The First Circuit's decision merits this Court's review. The court held that a relator can be an original source where his complaint largely rehashes allegations in prior litigation and fails to identify a single specific false claim or false record and where the relator did not inform the government of the alleged fraud before it was publicly disclosed. This holding squarely conflicts with holdings in four other federal circuits. The court also held that a relator

who alleges that a defendant caused a third party to file false claims need only allege facts sufficient to "strengthen the inference of fraud beyond possibility." Pet. App. 33a, 38a. That holding conflicts with this Court's precedent on Rule 8 and Rule 9(b), which makes clear that the First Circuit's Rule 9(b) standard requires nothing more than Rule 8 does. That holding also conflicts with at least three federal circuits that have rejected relaxing the Rule 9(b) standard for relators who assert they lack access to information needed to satisfy an unrelaxed standard.

These conflicts should be resolved now. Allowing relators to bring FCA claims that only rehash information already in the public domain, as Duxbury did here, betrays Congress's goal of limiting FCA *qui tam* suits to those who bring new fraud to light. And allowing FCA relators to survive Rule 9(b) merely by meeting the pleading requirements of Rule 8 eviscerates Rule 9(b)'s protections for defendants facing fraud charges. It is particularly perverse to permit Duxbury to proceed as an "original source" on the basis of his asserted "direct and independent knowledge" while at the same time abandoning the Rule 9(b) pleading standard to accommodate his supposed lack of information needed to plead with particularity core elements of the alleged fraud, including false claims.

I. The First Circuit's Construction Of The "Original Source" Exception To The Public Disclosure Bar Merits Further Review.

A. The Circuits Are Split On When A Relator Must Provide Information On An Alleged Fraud To The Government To Qualify As An Original Source.

The First Circuit's decision that, to qualify as an original source, a relator need not provide information to the government before the alleged fraud is publicly disclosed, though in accord with decisions of the Fourth and Eighth Circuits, *see United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1355 (4th Cir. 1994); *United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1050-51 (8th Cir. 2002), conflicts with holdings in four other circuits, *see* Pet. App. 17a (citing *Dick*, 912 F.2d 13 (2d Cir. 1990); *McKenzie*, 123 F.3d 935 (6th Cir. 1997); *Wang*, 975 F.2d 1412 (9th Cir. 1992); *Findley*, 105 F.3d 675 (D.C. Cir. 1997). Contrary to the First, Fourth, and Eighth Circuits, the Sixth and D.C. Circuits both require an original source to inform the government of fraud allegations *before* the allegations are publicly disclosed. *See, e.g.*, *McKenzie*, 123 F.3d at 942-43; *Findley*, 105 F.3d at 691. The Second and Ninth Circuits have similarly refused to qualify a relator as an original source, if the relator informs the government and files suit *only after* someone else has publicly disclosed the same fraud allegations, unless the relator "had a hand in the public disclosure of allegations that are a part of one's suit." *Wang*, 975 F.2d at 1418; *see Dick*, 912 F.2d at 18 (to surmount the public disclosure bar, "one must have

been a source to the entity that first publicly disclosed the information").[2]

In *Wang*, the Ninth Circuit addressed an FCA relator whose allegations of fraud had already been publicly disclosed. The relator had worked on a weapon system while employed by the defendant. After being fired, he informed the government of an alleged fraud involving the weapon system that newspapers had already independently revealed. He then filed an FCA suit repeating those allegations. The Ninth Circuit held that the relator was not an original source. Concluding that the text of the public disclosure bar is "ambiguous," the Ninth Circuit relied on the FCA's purpose and history in holding that *qui tam* jurisdiction "extend[s] only to those who . . . played a part in publicly disclosing the allegations and information on which their suits" are based. *Wang*, 975 F.2d at 1418. According to the Ninth Circuit, the FCA's *qui tam* provisions aim "to encourage insiders privy to a fraud on the

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[2] The holding in *United States ex rel. Cooper v. Blue Cross and Blue Shield of Fla., Inc.*, 19 F.3d 562, 568 (11th Cir. 1994), suggests that the Eleventh Circuit might agree with the First, Fourth and Eighth Circuits, although it did not expressly address the issue. The Fifth Circuit may also have used this approach, without analysis, in *United States ex rel. Fried v. W. Indep. Sch. Dist.*, 527 F.3d 439, 442-43 & n.2 (5th Cir. 2008). The Seventh Circuit has noted its disagreement with the Second and Ninth Circuits' requirement that an original source have a hand in any prior public disclosure. *See United States ex rel. Matthews v. Bank of Farmington*, 166 F.3d 853, 865 (7th Cir. 1999), *overturned on other grounds* 570 F.3d 907 (7th Cir. 2009).

government to blow the whistle on the crime." *Id.* at 1419. And the court reasoned that Congress accomplished that goal by "permit[ing] one who publicly disclosed the information to bring a *qui tam* suit." *Id.* This understanding of the FCA led the Ninth Circuit to follow the Second Circuit, *see Dick*, 912 F.2d at 16-18, in requiring that an original source "have had a hand in" any public disclosure preceding suit. *See Wang*, 975 F.2d at 1418; *United States ex rel. Lujan v. Hughes Aircraft Co.*, 162 F.3d 1027, 1034 (9th Cir. 1998) (explaining *Wang*).

The Sixth and D.C. Circuits' approach, while not requiring a relator to be the source of the public disclosure to qualify as an original source, also conflicts with the First Circuit's decision because it requires a relator to provide the government information about the fraud *before* any public disclosure. In *Findley*, the D.C. Circuit observed that "[v]irtually every court of appeals that has considered the public disclosure bar explicitly or implicitly agrees . . . [that] the language of the statute is not so plain as to clearly describe which cases Congress intended to bar." 105 F.3d at 681. It thus interpreted the "original source" provision based on the FCA's structure and congressional intent, as well as its language. In doing so, the court criticized the approach taken by the court of appeals here. That approach, according to the D.C. Circuit, renders part of the "original source" requirement "extraneous." 105 F.3d at 690-91. Another FCA provision already requires *every* relator to inform the government of the alleged fraud at the time of suit, and allows the government at least sixty days to consider the information. *See id.*; 31 U.S.C. § 3730(b)(2). Separately requiring an original source

to provide information to the government before filing suit would thus be "extraneous." *Findley*, 105 F.3d at 690-91. To avoid this result and honor Congress's intent that FCA relators be "whistleblowers" who *expose* fraud, the D.C. Circuit held that an original source must inform the government of the alleged fraud *before any public disclosure*. *Id.* at 690. This meant that the relator was not an original source because he provided no information to the government before "echo[ing]" publicly available allegations. *Id.* at 688 (internal quotation marks and citation omitted).

The Sixth Circuit adopted the same interpretation in *McKenzie*, relying on a detailed analysis of congressional purpose and the holding of *Findley*. *See* 123 F.3d at 942-43 (focusing on Congressional intent that FCA relators be "whistleblowers"). In *McKenzie*, the relator's allegations had been publicly disclosed in previously filed lawsuits. 123 F.3d at 943. Because the relator did not inform the government of her allegations before the public disclosures, the Sixth Circuit held that her *qui tam* action was barred. *Id.*

In rejecting that approach, the First Circuit reasoned that this Court's decision in *Rockwell*, 549 U.S. 457, "substantially undercuts the conclusion by the D.C. and Sixth Circuits that 'little incentive' is necessary for suits brought after a public disclosure." Pet. App. 22a. *Rockwell* did not address the questions presented here, however. Rather, it addressed the "direct and independent knowledge" requirement of the "original source" exception. *See* 31 U.S.C. § 3730(e)(4)(B) (requiring a relator to have "direct and independent knowledge of the information on which the allegations are based").

And *Rockwell*'s holding certainly cannot support the court's conclusion that the relator had direct and independent knowledge when his allegations were previously disclosed by someone else and he cannot allege a single specific false claim. *See* Linda Baumann, *Health Care Fraud and Abuse: Practical Perspectives*, at 297-98 (2d ed. 2007) (noting that, after *Rockwell*, a relator "must have firsthand information" and "essentially must be the employee on the shop floor" where the fraud occurs) ("Baumann").

Although the First Circuit concluded that the *Rockwell* Court's interpretation of the word "information" supported its resolution of the question, Pet. App. 24a, the Sixth and Ninth Circuits have continued explicitly to follow their rules in the wake of *Rockwell*. *See Poteet*, 552 F.3d at 515 (6th Cir.) (citing *McKenzie* and *Rockwell* in holding that relator's *qui tam* complaint "is jurisdictionally barred" partly because she failed to provide the government with the information underlying her complaint before the alleged fraud was publicly disclosed); *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1201-03 (9th Cir. 2009) (citing *Wang* and *Rockwell* in holding that relators were not original sources because, among other reasons, they did not establish that they "had a hand in the public disclosure"). Accordingly, this Court should grant review to resolve the circuit conflict that persists in the wake of *Rockwell*. *See* Boese, § 4.02[D], at 4-113 ("The decision in *Findley* demonstrates the deep divisions between the circuits on these complex jurisdictional bar issues. . . . [S]ection 3730(e)(4) clearly requires additional

clarification and the circuit splits are becoming more obvious.").

B. The "Original Source" Question Is Recurring and Important.

The circuit conflict on the "original source" exception is sufficiently important to warrant this Court's review. "Each of the original source provision's key terms has been interpreted and defined—generally in conflicting ways—in a number of cases. Indeed, since its enactment in 1986, the 'original source' rule has become (along with 'public disclosure') the most litigated—and confused—issue under the *qui tam* provisions." Boese, § 4.02[D], at 4-99.[3] That at least seven circuits have squarely addressed the question presented, with at least two circuits applying their approaches after *Rockwell*, *see Poteet* and *Meyer*, *supra*, illustrates that the issue is recurring. And the question is important because it implicates the federal subject-matter jurisdiction and because, as the United States explained in its amicus brief in the court of appeals, "proper application of the FCA's public disclosure bar is critical to enforcement of that statute." United States Brief, at 3. It is unfair to both relators and *qui tam* defendants to have the availability of an FCA action turn on the happenstance of geography. This Court

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[3] *See also* Transcript of Oral Argument at *21, *Graham County Soil and Water Conservation Dist. v. United States ex rel. Wilson*, No. 08-304, 2009 WL 4249114 (U.S. Nov. 30, 2009) (Justice Scalia alluding to the "random nature of the whole [public disclosure bar] provision").

should grant review to establish a uniform rule on when a relator must provide information to the government to qualify as an "original source."

C. The Decision Below Is Incorrect.

"Statutory construction must begin with the language employed by Congress and the assumption that the . . . language accurately expresses the legislative purpose." *Engine Mftrs. Ass'n v. S. Coast Air Quality Mgt. Dist.*, 541 U.S. 246, 252 (2004) (internal quotation marks and citation omitted). "[E]ven the most basic general principles of statutory construction," however, "must yield to clear contrary evidence of legislative intent." *Nat'l R.R. Passenger Corp. v. Nat'l Ass'n of R.R. Passengers*, 414 U.S. 453, 458 (1974). Moreover, "well-established principles of statutory interpretation . . . require statutes to be construed in a manner that gives effect to all of their provisions." *United States ex rel. Eisenstein v. City of New York*, 129 S. Ct. 2230, 2234 (2009). Contrary to these principles, however, the First Circuit's interpretation of the "original source" exception (1) conflicts with the FCA's purpose, and (2) renders a statutory provision of no practical effect.

In designing the FCA *qui tam* provisions, Congress sought to provide "adequate incentives for whistle-blowing insiders with genuinely valuable information," while "discourag[ing] . . . opportunistic plaintiffs who have no significant information to contribute of their own." *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 649 (D.C. Cir. 1994); *see also, e.g., Wang*, 975 F.2d at 1419 ("[FCA *qui tam*] suits are meant to encourage insiders privy to a fraud on the government to blow the whistle . . . . [T]here is little point in rewarding a

second toot."); *Dick*, 912 F.2d at 17 (observing that "a co-drafter of the legislation[] stated that a person is an 'original source' if, *inter alia*, the person 'had some of the information related to the claim which he made available to the government or the news media *in advance of the false claims being publicly disclosed*'" (quoting 132 Cong. Rec. H9389 (daily ed. Oct. 7, 1986) (statement of Rep. Berman) (emphasis in *Dick*)).

As the United States has explained, the First Circuit's construction of the 'original source' exception will permit FCA lawsuits by relators who, like Duxbury, "do little to assist the Government in identifying fraud" and thus do not facilitate proper enforcement of the statute. United States Brief, at 23. Indeed, it allows relators to avoid the public disclosure bar by providing the government with information on fraud the day before (or even minutes before) suing, when someone else has, as here, already disclosed the same allegations. The United States, the real FCA party in interest, has characterized this scenario as an "absurd" result of the First Circuit's approach. *See id.*; *see also* Michael Louks and Carol Lam, *Prosecuting and Defending Health Care Fraud Cases*, 2008 Cumulative Supplement, at 86 (criticizing the 4th Circuit minority view "in light of the history, structure, design, and intent" of the FCA). Permitting relators to pursue windfall recoveries for allegations of which the government is already aware—and may already be addressing—frustrates congressional intent to reward only those relators who are true "whistleblowers."

The First Circuit's interpretation also renders the "original source" requirement to provide information

to the government of no practical effect. Section 3730(b)(2) already requires *every* FCA relator to serve on the government a "copy of the complaint and written disclosure of substantially all material evidence and information the person possesses . . . ." As Judge Wald noted in *Findley*, 105 F.3d at 690-91, if a relator can satisfy the "original source" rule by providing information to the government just before filing, that rule would impose no meaningful obligation beyond what Section 3730(b)(2) requires.

The First Circuit's decision creates a rule that contravenes congressional intent, produces absurd results, and fails to give effect to every FCA provision. This Court should grant review and reject that rule in favor of the interpretation proposed by petitioner and the United States—one requiring an original source to inform the government of alleged fraud *before a public disclosure*. *See also* Baumann, at 286 (arguing that this view best interprets the "language, legislative history, and statutory purpose").

II. The First Circuit's Ruling Exempting A Significant Category Of FCA Relators From The Rigors Of Rule 9(b) Merits Further Review.

A. The First Circuit's Holding On Rule 9(b) Conflicts With This Court's Precedent, And Circuits Are Split Over What Rule 9(b) Requires.

The First Circuit held that a relator alleging that a defendant caused a third party to submit false claims is entitled to a "more flexible [Rule 9(b)] standard," Pet. App. 35a, under which the

allegations need only contain "factual . . . evidence to strengthen the inference of fraud beyond possibility." *id.* at 33a, 38a (internal quotation marks omitted). That holding merits further review because it conflicts with this Court's precedent and with holdings of other federal circuits.

This Court's recent pleading-standard cases make clear that Rule 8 already requires "sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570). As this Court explained in *Iqbal*, the Rule 8 "plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S. Ct. at 1949 (citation omitted). That "plausibility standard" can be met, this Court held, "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citation omitted).

The First Circuit's "more flexible [Rule 9(b)] standard" is indistinguishable from the generally applicable Rule 8 standard, as construed by *Iqbal* and *Twombly*. The First Circuit did not provide a clear rationale for exempting a *qui tam* relator from the more "rigid," "elevated pleading standard" of Rule 9(b), *Iqbal*, 129 S. Ct. at 1954, which requires that allegations of fraud be pleaded with particularity. However, the First Circuit suggested that it based its application of the relaxed standard on the "distinction between a qui tam action alleging that the defendant made false claims to the government, and a qui tam action in which the defendant induced *third parties* to file false claims with the government." Pet. App. at 32a (citing *Rost*,

507 F.3d at 732 (construing the latter action as "in a different category" from the former)).

The First Circuit's "more flexible standard" also conflicts with decisions of other circuits. Under the First Circuit's approach, if an FCA relator alleges that a defendant induced a third party to file false claims, the relator, like Duxbury here, can satisfy Rule 9(b) without identifying a single "false or fraudulent claim," even though such a claim is a core element of FCA fraud. *See* Pet. App. 36a (acknowledging that "Duxbury does not identify specific claims").[4]

Other courts of appeals have held that a relator alleging FCA fraud must identify a false claim and have refused to create an exception, as the First Circuit has done, for a relator who contends that he lacks the necessary access to specify false claims with particularity. In *Joshi*, 441 F.3d at 560, the Eighth Circuit held that an FCA relator must specify "*some* representative examples" of false claims to support allegations of a wide-ranging fraud. In so holding, the court expressly rejected the relator's

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[4] Duxbury conceded that he "cannot identify at this time all of the false claims caused by Defendant. The false claims were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control." Pet. App. 102a (Am. Compl. ¶ 232). As the district court noted, however, Rule 9(b)'s very purpose is to ensure that a plaintiff has sufficient information that a defendant committed fraud to justify permitting the potentially damaging suit to proceed. Pet. App. 76a. And while Duxbury alleged that he was unable to identify "all of the false claims," he actually identified none.

request "to relax Rule 9(b)'s pleading requirements by allowing him to plead his complaint generally at the outset and to 'fill in the blanks' following discovery." *Id.* at 559.

The relator offered several reasons to justify his request: that the "fraudulent scheme was complex, the fraudulent conduct took place over a long period of time, and information concerning the alleged fraud is uniquely within the defendants' control." *Id.* at 560. The Eighth Circuit rejected all of them.

Recognizing that the relator, who was not a member of the defendant's billing or claims department, "may not have [been] privy to certain details relevant to his complaint," the court noted the oddity of an FCA relator requesting special leniency under the pleading rules, observing that "[t]he [FCA] is intended to encourage individuals who are either close observers or involved in the fraudulent activity to come forward, and is not intended to create windfalls for people with secondhand knowledge of the wrongdoing." *Id.* at 561 (internal quotation marks and citation omitted); *see also id.* at 560 (observing that the relator's request for a relaxed pleading standard "conflicts with his allegation [that] he is an 'original source'"). The court also expressed concern that relaxing Rule 9(b) would undermine the important protections it offers defendants, including preventing needless harm to a defendant's "goodwill and reputation" wrought by "a suit that is, at best, missing some of its core underpinnings, and, at worst," makes "baseless allegations . . . to extract settlements." *Id.* at 559 (internal quotation marks omitted). This concern is especially applicable to FCA actions, the court explained, because "a qui tam plaintiff, who has suffered no injury in fact, may be

particularly likely to file suit as a pretext to uncover unknown wrongs." *Id.* (internal quotation marks and citation omitted).

Finally, the Eighth Circuit concluded that allowing a relaxed Rule 9(b) standard would be "inconsistent with the relator's procedural obligations under the FCA," which require a relator to "serve a copy of the complaint on the government and disclose all material evidence and information known to the relator in order to allow the government to decide whether or not to intervene." 441 F.3d at 559-60. All of the reasons that the Eighth Circuit identified for rejecting a relaxed Rule 9(b) standard in FCA cases apply to a relator, such as Duxbury, who alleges difficulty identifying false claims that third parties allegedly filed.

The Sixth and Eleventh Circuits have also required relators to specify false claims, and have expressed a willingness to relax that requirement if, and only if, the relator adequately alleges that information needed to identify a false claim is *exclusively* within the *defendant's* control. In *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003), the Sixth Circuit expressly rejected relaxing Rule 9(b), where, as here, "third parties possess information concerning the [alleged fraud at issue]." In so holding, the court observed that "[t]he requirement that fraud be plead[ed] with particularity need not be relaxed in FCA cases in order to protect the public because the government's ability to intervene on the basis of information brought to its attention vindicates the public interest." *Id.* at 563.

In *United States ex rel. Clausen v. Laboratory Corp. of America*, the Eleventh Circuit similarly held that a relator failed Rule 9(b) because his complaint failed to contain "some indicia of reliability . . . to support the allegation of an *actual false claim* for payment being made to the Government." 290 F.3d 1301, 1311 (11th Cir. 2002). The relator offered no "examples of actual false claims"—the "*sine qua non* of a False Claims Act violation"—and the court concluded that the relator's allegations were merely "conclusory statements . . . [that] d[id] not adequately allege when—or even if—the schemes were brought to fruition." *Id.* at 1311-12, 1314 n.25, 1315. The Eleventh Circuit rejected the notion that Rule 9(b) should be relaxed to account for the fact that the relator was not in a position to know the details of the false claims. The court explained that "while an insider might have an easier time obtaining information about billing practices . . ., neither the Federal Rules nor the [FCA] offer any special leniency" to an "outsider" who "fail[s] to allege with the required specificity the circumstances of the fraudulent conduct he asserts in his action." *Id.* at 1314.[5] *See also United States ex rel. Lacy v.*

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[5] The application of the "indicia of reliability test" in the Eleventh Circuit has generally required the identification of specific false claims. *See, e.g., United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1358-60 (11th Cir. 2006). In two exceptional cases, the court concluded that the relator met that test, through detailed allegations of first-hand knowledge of such things as improper billing codes and billing procedures. *See United States ex rel. Walker v. R&F Props. of Lake County, Inc.*, 443 F.3d 1349, 1360 (11th Cir. 2005); *Hill v. Morehouse Med. Assocs., Inc.*, No. 02-14429, 2003 WL 22019936, at *4-5 (continued...)

New Horizons, Inc., No. 08-6248, 2009 WL 3241299, at *3 (10th Cir. Oct. 9, 2009) (affirming dismissal of FCA claim under Rule 9(b) because the relator "has supplied no specific details concerning *any particular false claim*").[6]

Under the Sixth, Eighth and Eleventh Circuit standards, Duxbury's allegations would clearly fail Rule 9(b). He did not plead with particularity any false claims or any false statements or records linked to such claims, and Duxbury does not allege that the information needed to plead such particulars is exclusively within OBP's control. The First Circuit nevertheless held that Duxbury's allegations survive

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(11th Cir. Aug. 15, 2003) (unpublished). The Eleventh Circuit has rejected subsequent attempts to extend or broaden the narrow exception recognized in such cases. *See, e.g., United States ex rel. Shurick v. Boeing Co.*, 330 Fed. Appx. 781, 784 (11th Cir. 2009) (unpublished) ("[Relator's] complaint fails to state a claim because it does not allege with particularity the submission of a fraudulent claim . . . [and relator] lacks personal knowledge of the invoices and fails to allege facts that establish that invoices were actually submitted . . . ."); *Atkins*, 470 F.3d at 1359 ("The particularity requirement of Rule 9[(b)] is a nullity if Plaintiff gets a ticket to the discovery process without identifying a single claim.") (citations omitted).

[6] In *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), the Fifth Circuit held that relators who "cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. This "strong inference" test offers yet another approach to Rule 9(b) in FCA cases.

under a "more flexible [Rule 9(b)] standard" that requires a relator's pleadings to do nothing more than satisfy Rule 8 and whose *apparent* justification is one that these other circuits have roundly rejected—namely, that the relator is simply not in a position to know the details of any false claim that was allegedly submitted, or false record or statement linked to a false claim. This Court should grant review to resolve the conflict between the First Circuit's approach and precedents of this Court and other circuits.

B. The Rule 9(b) Question Is Recurring And Important.

By screening out allegations of fraud that are not sufficiently particularized, Rule 9(b) serves an important gate-keeping function that protects defendants from harassing "strike suits" and "fishing expeditions" that impose on courts, parties, and society "enormous social and economic costs." *See Bly-Magee*, 236 F.3d at 1018. Rule 9(b) plays an especially important role in FCA cases, where relators seek the privilege of stepping into the shoes of the federal government to pursue potentially ruinous damage awards against defendants. The First Circuit has exempted a significant category of FCA relators from the rigors of Rule 9(b) on the paradoxical theory that these relators deserve special leniency as to key aspects of the alleged fraud. The First Circuit's rule merits this Court's review to address a circuit split and because it deprives FCA defendants of the critical protections to which they are entitled under Rule 9(b).

C. The First Circuit's Decision On Rule 9(b) Is Incorrect.

The First Circuit's "more flexible [Rule 9(b)] standard" for FCA relators, allowing relators to survive Rule 9(b) by pleading facts that "strengthen the inference of fraud beyond possibility," Pet. App. 33a, 38a, conflicts with this Court's decisions in *Twombly* and *Iqbal*. Those cases construe Rule 8 to require *all* plaintiffs to plead facts showing that their right to relief is more than a mere possibility. *See Iqbal*, 129 S. Ct. at 1954; *Twombly*, 550 U.S. at 557.

The First Circuit did not identify any justification for exempting a category of relators from the rigors of Rule 9(b). The apparent rationale—that a relator alleging that the defendant caused a third party to file false claims is not in position to know the details of the claims allegedly filed by the third party—is unpersuasive. "Since Rule 9(b) is a pleading requirement, not a 'capacity of the party' requirement, the identity or insider status of the relator is not a proper basis for relaxing the rigorous pleading requirements that apply to all FCA complaints." Boese, § 5.04[B][2], at 5-62.5 – 5-62.6. Moreover, the false claim under Section 3729(a)(1)(A) (and the "false record or statement material to a false or fraudulent claim" under Section 3729(a)(1)(B)) is the key element of the cause of action, and the FCA is designed to reward those with *knowledge* of the fraud, not those seeking to discover whether there was a fraud. *See* Boese, § 5.04[C], at 5-62.13 – 5.63 ("[T]he better-reasoned [Rule 9(b)] decisions . . . hold that Rule 9(b) should prohibit fraud actions in which the facts must be learned through discovery."). It is especially anomalous to

exempt from Rule 9(b) a relator such as Duxbury, and then qualify him as an original source, who asserts that he has direct and independent knowledge of the alleged fraud and "specific knowledge" of false claims. *See* Pet. App. 95a (Am. Compl. ¶ 211). Someone with such knowledge should need no relaxed rule to plead fraud with particularity.

Under Rule 9(b), the "circumstances constituting fraud" must be stated with particularity. Fed. R. Civ. P. 9(b). Those circumstances include "a false or fraudulent claim." *See* 31 U.S.C. § 3729(a)(1)(A)-(B) (and also, under § 3729(a)(1)(B), "a false record or statement" material to "a false or fraudulent claim"). Under the most natural reading of Rule 9(b), as several courts of appeals have held, *see supra* Part II.A, this means that an FCA plaintiff must allege facts that in some way identify a *particular* "false or fraudulent claim." Duxbury did not do this.

FCA *qui tam* suits "are meant to encourage *insiders privy to a fraud on the government* to blow the whistle . . . . [S]uch insiders should be able to comply with Rule 9(b)." *Bly-Magee*, 236 F.3d at 1019 (internal quotation marks and citation omitted). Because Duxbury has not done so, the First Circuit should have affirmed the district court's dismissal of his "kickback" allegations under Rule 9(b).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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December 3, 2009

APPENDIX A

United States Court of Appeals
For the First Circuit

No. 08-1409

UNITED STATES, ex rel. Mark Eugene Duxbury and Dean McClellan,

Plaintiffs,

MARK EUGENE DUXBURY; DEAN MCCLELLAN,

Plaintiffs, Appellants,

v.

ORTHO BIOTECH PRODUCTS, L.P.,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Rya W. Zobel, U.S. District Judge]

Before

Torruella, Circuit Judge,
Siler,* Senior Circuit Judge,
and Howard, Circuit Judge.

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* Of the Sixth Circuit, sitting by designation.

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Cleveland Lawrence III, on brief as amicus curiae of Taxpayers Against Fraud Education Fund in support of appellants.

August 12, 2009

TORRUELLA, Circuit Judge. This appeal concerns the qui tam provisions of the False Claims Act (the "FCA"), 31 U.S.C. § 3730, which allow whistleblowers (called "relators") to bring certain fraud claims on behalf of the United States.[1] The relators in this case, the plaintiffs-appellants Mark Duxbury and Dean McClellan (together, the "Relators"), alleged that defendant-appellee Ortho Biotech Products, L.P. ("OBP") violated the FCA in unlawfully promoting the sale of its drug Procrit. The district court dismissed all of the Relators' claims, and this appeal followed. After careful consideration, we affirm in part and reverse in part.

I. Background

A. The FCA

To provide context, we start with the statutory scheme. The FCA contains qui tam provisions that "supplement federal law enforcement resources by encouraging private citizens to uncover fraud on the government." Rost, 507 F.3d at 727. The qui tam

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[1] As we have previously noted:

> "Qui tam" comes from the phrase "qui tam pro domino rege quam pro se ipso in hac parte sequitur," which translates as "who pursues this action on our Lord the King's behalf as well as his own."

United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 n.4 (1st Cir. 2007) (quoting Rockwell Int'l Corp. v. United States, 549 U.S. 457, 463 n.2 (2007)), overruled on other grounds by Allison Engine v. United States ex rel. Sanders, 128 S. Ct. 2123 (2008).

provisions permit whistleblowers (known as relators) to bring certain fraud claims on behalf of the United States; in return, "[a] private relator is entitled to a portion of any proceeds from the suit, whether the United States intervenes as an active participant in the action or not." Id. at 727.

"The qui tam mechanism has historically been susceptible to abuse, however, by 'parasitic' relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise uncover." Id. Accordingly, Congress has amended the FCA several times "to walk a fine line between encouraging whistle-blowing and discouraging opportunistic behavior." See United States ex rel. S. Prawer v. Fleet Bank of Me., 24 F.3d 320, 324-26 (1st Cir. 1994) (quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994) (detailing the history of such amendments to the FCA's qui tam provisions)).

As a result of these amendments, the FCA includes jurisdictional bars that limit a district court's subject matter jurisdiction over qui tam actions. Two of these bars are relevant to this action. The first, known as the "public disclosure" bar, provides that a court does not have subject matter jurisdiction over any qui tam action that is "based upon the public disclosure of allegations or transactions" concerning the alleged fraud, unless, among other things, "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A). A relator qualifies as an "original source" if (1) she has "direct and independent knowledge" of the information supporting her claims and (2) she "provided the information to the Government before filing an action." Id.

§ 3730(e)(4)(B). The second, known as the "first-to-file" bar, provides that when a potential relator brings an FCA action, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." Id. § 3730(b)(5).

B. The Complaints

OBP distributes and promotes Procrit -- the brand name for epoetin alfa -- a drug approved by the FDA for use to treat anemia resulting from chemotherapy, chronic kidney disease, HIV infection, and blood loss from certain types of surgery. Both Relators were sales representatives for OBP who were responsible for the promotion and sale of Procrit in the Western United States. From 1992 to 1998, OBP employed Relator Duxbury, first as a Product Specialist and later as a Regional Key Account Specialist for OBP's Western Division Oncology sales force. From 1992 to 2004, OBP employed Relator McClellan, also first as a Product Specialist but later as a Territory Manager for OBP's Western Division Oncology sales force.

This appeal turns on a number of complaints filed by the Relators and other parties, which we discuss in some detail below.

On November 6, 2003, Duxbury, but not McClellan, filed a complaint (the "Original Complaint") in the District Court for the District of Massachusetts. The Original Complaint contained allegations concerning OBP's fraudulent reporting of the Average Wholesale Price ("AWP") of Procrit, a benchmark used by the Medicare program for reimbursement purposes. It was filed hot on the

heels of a master consolidated complaint (the "MCC") filed in September 2002 in a multi-district litigation concerning the fraudulent reporting of AWP. See generally In re Pharm. Indus. Average Wholesale Price Litig., MDL No. 1456, No. 01-12257-PBS (the "AWP MDL").[2]

The Original Complaint contained two counts, one alleging "substantive violations" of the FCA and the other a conspiracy count. (Compl. ¶¶ 47-55 (Count I); id. ¶¶ 56-60 (Count II)). In support of the counts, the Original Complaint alleged that OBP published a fraudulently inflated AWP for Procrit, which resulted in the filing of false claims for reimbursement with the Medicare program. (Id. ¶¶ 1, 29). The Original Complaint further alleged that OBP marketed the "spread" -- the difference between the higher, fraudulent AWP and the lower, actual cost of Procrit -- to induce medical providers to purchase Procrit. (Id. ¶¶ 23, 29). Thus, according to the Original Complaint, the "spread" not only caused the filing of false claims, but constituted an "illegal kickback" to health care providers. (Id. ¶¶ 23, 30).

The Original Complaint also alleged that OBP provided "free samples" of Procrit as well as "non-public financial inducements," such as rebates, discounts, "unrestricted education grants," and "phony drug studies." (Id. ¶¶ 31, 34, 38, 40, 43).

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[2] For background concerning the AWP MDL, which is quite complex, see In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007).

OBP allegedly used these inducements "to lower the providers' net cost of purchasing Procrit," and further "inflate[] the AWP," as "the value of these services was kept off the book, so as not [to] be reflected in the AWP." (Id. ¶ 34; see also id. ¶¶ 32-33). The Original Complaint alleged that these inducements also constituted illegal kickbacks. (See id. ¶¶ 3, 45).

With respect to the "phony drug studies," the Original Complaint alleged at Paragraphs 40 through 42 that OBP utilized "Phase IV Marketing Trials" to, among other things, "encourage the physician, clinic, or hospital to use the drug in a way which [wa]s inconsistent with its FDA approved indications and administration methods." (Id. ¶ 40(c)). The Original Complaint referred specifically to a 1997 trial in which OBP allegedly

> paid physicians to dose Procrit at 40,000iu in a once per week dose instead of the FDA approved dosage of 10,000iu three times per week dosage in cancer-chemotherapy patients. The trial was very successful and the once per week dosage is now universally accepted among oncologists. The trial's success also resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week -- an increase in 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia.

(Id.) (emphasis in original). The Original Complaint further alleged that "[t]he 40,000iu dosage scheme was successful for Ortho and doctors, but Ortho ha[d]

not received FDA approval for such dosage." (Id. ¶ 41) (emphasis in original).

On December 19, 2003, about one month after the filing of the Original Complaint, Kurt Blair, also a former OBP sales representative, filed a qui tam complaint (the "Blair Complaint") against OBP in the District Court for the District of Colorado. The Blair Complaint contained two counts. Count I alleged that, beginning in 1998, OBP promoted "a dosing regimen of 40,000 units once per week" even though it had not received approval from the FDA for such a high dosage. (Blair Compl. ¶¶ 22-27). Blair claimed that OBP promoted this unapproved, "off-label" dosage through a variety of means, such as direct off-label marketing to medical professionals; influencing the results of purportedly independent clinical studies; and rebate programs offered to induce increased prescriptions of Procrit, among other things. (Id. ¶¶ 27, 28-79). Blair alleged that OBP's promotion of this off-label use caused the filing of "false" claims for reimbursement with Medicare and Medicaid, insofar as the providers sought reimbursement for "nonreimburseable" uses. (Id. ¶¶ 88-91). Count II alleged that OBP caused the submission of false claims by, among other things, "paying thousands of kickbacks to Medicaid and Medicare providers, causing the providers to write tens of thousands of prescriptions for Procrit that would otherwise not have been written." (Id. ¶ 93).

As required under the FCA, both the Original Complaint and the Blair Complaint were filed under seal to allow the United States time to review both

complaints and decide whether to intervene. 31 U.S.C. § 3730(b)(2).[3] On March 23, 2004, the Blair district court allowed the government's motion to partially lift the seal on the Blair Complaint in order to disclose it to Duxbury.

On July 18, 2004, Duxbury, through his counsel, provided a written disclosure of information (the "Information") to the Department of Justice (the "DOJ"). The Information was sent in response to a April 6, 2004 letter by the DOJ summarizing the allegations in the Original Complaint and requesting further information. The Information stated that "[w]e believe the following paragraph describes a more important and damaging fraud identified in Mr. Duxbury's complaint, which we described (see Complaint ¶¶ 40-42) but are not sure you have grasped based on your letter and the interview of Mr. Duxbury." The "following paragraph" stated in part:

> In 1997, [OBP] initiated an intentional scheme to promote an illegal, off-label dosage of

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[3] 31 U.S.C. § 3730(b)(2) provides in full:

> A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(footnote omitted).

> Procrit for cancer patients that would increase sales and federal reimbursements by approximately a third. [OBP]'s scheme worked, and starting in around 1999 Medicare began reimbursing for Procrit at a one-third higher dosage than it had previously, without FDA approval for this dosage and contrary to the Medicare Act's rules for reimbursement of cancer drugs. The injury to the Medicare program alone is in the hundreds of millions.

The Information then went on to discuss this "scheme" in more detail.[4]

On July 12, 2005, after an investigation, the DOJ declined to intervene in the Original Complaint. On December 5, 2005, the Blair Complaint was voluntarily dismissed and subsequently unsealed in full.

On October 26, 2006, over OBP's objection, the district court allowed Duxbury's motion to amend the Original Complaint, and the next day, on October 27, 2006, both Relators filed a First Amended Complaint (the "Amended Complaint"). The Amended Complaint added Relator McClellan as a party and alleged three counts, two of which are at issue on this appeal.[5] (Am. Compl. ¶¶ 3, 227, 249, 270).

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[4] Duxbury asserts that the Blair Complaint had not been disclosed to him prior to the submission of the Information.

[5] Count II of the Amended Complaint alleges that OBP engaged in a scheme to publish a fraudulently inflated AWP for Procrit. On June 27, 2007, the parties jointly stipulated to the dismissal of this count.

Count I alleges that, beginning in December 1992 to the present, OBP engaged in a scheme to provide kickbacks to health care providers "to induce them to prescribe ProCrit." (Id. ¶¶ 228-232). The kickbacks allegedly included "free ProCrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria." (Id. ¶ 228). The Amended Complaint alleges that the kickbacks, among other things, "caused providers and hospitals to submit false claims for payment to Medicare for ProCrit." (Id. ¶¶ 229, 243-244).

Count III alleges that, beginning in 1997, OBP unlawfully promoted "[t]he administration of ProCrit at 40,000 units 1X per week to oncology patients," which "was not approved by the FDA." (Id. ¶¶ 131, 271, 273). Thus, the Amended Complaint alleges that OBP's "inflated dosing scheme was a substantial factor causing the submission of false claims for payment for ProCrit," insofar as OBP "caused providers and hospitals to administer ProCrit to chemotherapy patients at 40,000 units 1X/week[], and in the absence of [OBP's] scheme they would have administered ProCrit at 10,000 IU 3X/week." (Id. ¶ 282).

C. The Dismissal of the Amended Complaint

On January 17, 2007, OBP moved to dismiss the Amended Complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) and, in the alternative, for failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b). On January 28, 2008, the district court allowed OBP's motion to dismiss with prejudice and entered judgment in OBP's favor. See United

States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 551 F. Supp. 2d 100 (D. Mass. 2008).

As to Count I, the district court first held that the kickback claims were "based upon" a "public disclosure," in this case the "allegations" contained in the MCC filed in the AWP MDL, which also alleged the use of illegal kickbacks. See id. at 105- 08. The district court further held that Duxbury "qualifies as an original source" for the kickback claims, but only for those claims that occurred during his period of employment, 1992 through 1998, since "his direct knowledge of OBP's activities only extends to the time he was employed by the company." Id. at 109. Having established its subject matter jurisdiction, the court nevertheless dismissed the 1992 through 1998 kickback claims because the Amended Complaint failed to plead the claims with sufficient particularity under Rule 9(b). Id. at 115-16.

As to the kickback claims from 1998 to the present, the district court held that McClellan did not qualify as an "original source," as the Amended Complaint did not sufficiently allege that McClellan offered information concerning the kickback claims to the government prior to the filing of the Original Complaint. Id. at 109-10. Relatedly, and in the alternative, the district court found that, even if McClellan qualified as an original source, his claims were barred by the "first-to-file" bar because he asserted his kickback claims after the filing of the Original Complaint. Id. at 110.

As to Count III, the court dismissed the claims concerning "off-label" promoting because they were barred by the "first-to-file" rule. Id. at 110-14. The district court first held that, even though Paragraphs

40 through 42 of the Original Complaint mentioned unlawful off-label promotion, the Original Complaint did "not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit." Id. at 114. Thus, the district court considered the Blair Complaint the "'first' complaint to allege claims based upon OBP's alleged off-label marketing of Procrit," and accordingly dismissed the off-label promoting claims in Count III of the Amended Complaint. Id.

As no claims survived, the district court dismissed the Amended Complaint with prejudice as to the Relators. Relators now appeal.

II. Discussion

The district court dismissed a portion of Count I and all of Count III for lack of subject matter jurisdiction. Thus, "[w]e review the district court's determination that it lacked subject matter jurisdiction de novo." Muskat v. United States, 554 F.3d 183, 194 (1st Cir. 2009). Subject matter jurisdiction in this case is based on the allegations contained in the Amended Complaint. See Rockwell, 549 U.S. at 473. Accordingly, "we take as true all well-pleaded facts in the [Amended Complaint], scrutinize them in the light most hospitable to the plaintiffs' theory of liability, and draw all reasonable inferences therefrom in the plaintiffs' favor." Fothergill v. United States, 566 F.3d 248, 251 (1st Cir. 2009), see also id. at 251 n.1 (noting that "[t]his standard applies to motions to dismiss for want of subject-matter jurisdiction that are adjudicated on the pleadings, in advance of jurisdictional discovery and without the taking of any evidence."). "[W]e may affirm an order of dismissal on any ground made

apparent by the record (whether or not relied upon by the lower court)." Aguilar v. U.S. Immig. & Customs Enf., 510 F.3d 1, 8 (1st Cir. 2007).

The district court dismissed the remaining portion of Count I under Federal Rule of Civil Procedure 9(b) for failure to plead fraud with sufficient particularity. We similarly "review de novo the district court's dismissal order for failure to comply with Rule 9(b)." United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009).

A. Count I

The Relators contend that the district court erred in dismissing the kickback claims contained in Count I, which the court dismissed, in part, based on the "public disclosure" bar, and, in part, based on Rule 9(b).

"The threshold question in a False Claims Act case is whether the statute bars jurisdiction." Rost, 507 F.3d at 727. The district court's dismissal of the kickback claims turns on the "public disclosure" bar, set forth at 31 U.S.C. § 3130(e)(4). It provides:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or [General] Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(A) & (B) (emphasis added).

As we discussed in Rost, analysis of the "public disclosure" bar "requires several inquiries":

> (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint;
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> (2) if so, whether the public disclosure occurred in the manner specified in the statute;
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> (3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and
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> (4) if the answers to these questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B).

507 F.3d at 728. On appeal, the Relators do not challenge the district court's holding that the kickback claims contained in Count I are "based upon the public disclosure of allegations . . . in a . . . civil . . . hearing," in this case the allegations of illegal kickbacks contained in the MCC filed in the AWP MDL. Thus, we turn our attention to the fourth question, whether the Relators fall within the "original source" exception as defined in § 3730(e)(4)(B).

1. The "Provided" Language in the Original Source Exception

On appeal, OBP and the United States, appearing as an amicus, propose an alternative ground to affirm the dismissal of Count I. Under the FCA, an "original source" is defined as:

> an individual who has [1] direct and independent knowledge of the information on which the allegations are based and [2] has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(B) (emphasis added). In determining whether the Relators qualified as original sources, the district court held that "[t]he plain language of the FCA only requires the relator to provide his information to the government prior to filing his action," and that "[t]his unambiguous statutory language must guide the court's interpretation." Duxbury, 551 F. Supp. 2d at 109.

Both OBP and the United States argue that this was error, and contend that 31 U.S.C. § 3730(e)(4)(B) requires a relator to provide the information to the government before the public disclosure itself, not just before the filing of the relator's suit. As there is no allegation in the Amended Complaint that either McClellan or Duxbury provided any information concerning their kickback claims to the government prior to the public disclosure of the kickback allegations in the AWP MDL, both OBP and the government contend that we can affirm the dismissal of the kickback claims on this alternative ground. As explained in more detail below, and after a careful

analysis of the FCA, we disagree, and conclude that the district court's interpretation is the correct one.

We have not addressed the meaning of "provided the information to the Government before filing an action" under § 3730(e)(4)(B), but the issue has divided the courts. The Fourth Circuit, consistent with the district court, has held that § 3730(e)(4)(B) "requires only that the relator . . . voluntarily provide the information to the government before filing his qui tam action." United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1351 (4th Cir. 1994) (emphasis in original). The Second and Ninth Circuits have outlined a second approach, holding that the relator "must have directly or indirectly been a source to the entity that publicly disclosed the allegations on which a suit is based." United States ex rel. Dick v. Long Island Lighting Co., 912 F.2d 13, 16 (2d Cir. 1990); see also United States ex rel. Wang v. FMC Corp., 975 F.2d 1412, 1419 (9th Cir. 1992). The D.C. and Sixth Circuits have taken a third approach that stakes out a middle ground, holding that "an 'original source' must provide the government with the information prior to any public disclosure," but not requiring the relator to be the cause of the public disclosure. United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 690 (D.C. Cir. 1997); see also United States ex rel. McKenzie v. BellSouth Telecomms., Inc., 123 F.3d 935, 942-43 (6th Cir. 1997). OBP and the United States urge us to take this middle approach.

Although we are about to travel a well-trodden path, our first step remains the same. "Our first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the

case." Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." Id. at 341.

By its terms, the "original source" exception only requires the relator to "provide[] the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). Section 3730(e)(4)(B) does not impose any other timing requirement. Nor does § 3730(e)(4)(A). Thus, like the Fourth Circuit and the district court below, we conclude that the plain terms of § 3730(e)(4)(B) begin and end the matter. See Robinson, 519 U.S. at 340 ("Our inquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.'" (quoting United States v. Ron Pair Enters., Inc., 489 U.S. 235, 240 (1989))).

The government argues that the language of § 3730(e) (4)(B), when read in context, supports its view. Following the D.C. Circuit, the government points to the meaning of the terms "original source" itself, contending that a "source" is defined as "[t]he originator or primary agent of an act, circumstance, or result." Black's Law Dictionary 1522 (9th ed. 2009) (using the example "she was the source of the information."). Thus, a source cannot "originat[e]" information that has been publicly disclosed. The D.C. Circuit similarly found significance in "Congress's decision to use the term 'original source' rather than simply incorporating subparagraph (B)'s description into subparagraph (A)." Findley, 105 F.3d at 691.

However, we decline to rely upon the plain meaning of the terms "original source" when the statute defines the term at § 3730(e)(4)(B). It is only "[w]hen a word is not defined by statute" that we "construe it in accord with its ordinary or natural meaning." See Smith v. United States, 508 U.S. 223, 228 (1993). In addition, we decline to attribute significance to Congress's use of the terms "original source" rather than engraft the definition found at § 3730(e)(4)(B) into § 3730(e)(4)(A). Section 3730(e)(4)(A) sets forth two exceptions to the "public disclosure" bar, (1) when the relator is an "original source" and (2) when "the action is brought by the Attorney General." Thus, setting forth the definition of one of these exceptions in a separate subparagraph, rather than shoehorning it into § 3730(e)(4)(A), avoids unnecessary confusion and does not imply anything further. Finally, had Congress intended to retain the plain meaning of "original source" and require relators to provide their information prior to the public disclosure, "it easily could have done so." See Rost, 507 F.3d at 729 (rejecting argument that, for purposes of the meaning of "public disclosure," "equates the government with the public").

Typically, we end our review when "the plain language of a statute unambiguously reveals its meaning, and the revealed meaning is not eccentric." United States v. Meade, 175 F.3d 215, 219 (1st Cir. 1999) (noting that, in such circumstances, "courts need not consult other aids to statutory construction"). OBP and the government, however, argue that such an eccentricity would result.

Both OBP and the government primarily argue that interpreting the "provided" language in

§ 3730(e)(4)(B) by its plain terms would conflict with the intent of Congress. See United States v. Am. Trucking Ass'n, 310 U.S. 534, 542 (1940) ("In the interpretation of statutes, the function of the courts is . . . to construe the language so as to give effect to the intent of Congress."). Specifically, they argue that reading § 3730(e)(4)(B) by its plain terms would permit relators to bring suit based upon fraud that was already publicly disclosed, so long as the relator had "direct and independent knowledge" of the fraud. For example, a relator who learns about fraud against the government in the Huffington Post would be permitted to bring a qui tam suit "based upon" that "public disclosure" if she has "direct and independent knowledge" of the fraud and provides that information to the government before filing suit, literally the day before filing. The same would be true if the "public disclosure" resulted from a long-standing government investigation, where a relator would be entitled to bring suit so long as he or she had "direct and independent" knowledge of the public disclosure.

The D.C. Circuit concluded that, although the FCA provides financial incentives to provide information about fraud to the government, "[o]nce the information has been publicly disclosed, however, there is little need for the incentive provided by a qui tam action." Findley, 105 F.3d at 691. The Sixth Circuit discusses this point in more detail, holding that requiring a relator to disclose his or her information to the government prior to the public disclosure at issue advances the twin goals of (1) alerting the government to potential fraud and (2) creating incentives to do so as early as possible.

McKenzie, 123 F.3d at 942-43. As put by the Sixth Circuit,

> [T]his approach furthers Congress's . . . goal in amending the FCA: "[T]o prevent 'parasitic' qui tam actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of public fraud." Siller, 21 F.3d at 1347. Anyone who alerts the government and is a "true whistleblower" deserves any reward that may be obtained by pursuing a qui tam action under the FCA. However, the individual who sits on the sidelines while others disclose the allegations that form the basis of her complaint should not be able to participate in any award. This would be contrary to the purpose of the statute.

Id. at 943; see also Wang, 975 F.2d at 1419 ("Qui tam suits are meant to encourage insiders privy to a fraud on the government to blow the whistle on the crime. In such a scheme, there is little point in rewarding a second toot."). Thus, both OBP and the government argue that requiring the relator to provide his or her information before the public disclosure corrects this problem and ensures that only productive suits are filed, that is, those suits in which a "true whistleblower" alerts the government of fraud not publicly disclosed.

After careful consideration of the arguments in favor of adopting the middle approach, we conclude that honoring the plain and unambiguous meaning of § 3730(e)(4)(B) would not conflict with the intent of Congress. Our decision is supported by our own

review of the "language, structure, and history" of § 3730(e)(4)(B) and the "public disclosure" bar. See Rost, 507 F.3d at 728-29 (reviewing the language, structure and history of the terms "public disclosure" in rejecting interpretation that conflicted with the plain meaning of the statute). As we have just discussed the language of § 3730(e)(4)(B), we turn to the structure and history of the statute.

i. Structure

The structure of the FCA mitigates many of the concerns that lead the D.C. and Sixth Circuits to adopt the middle approach and, in fact, demonstrates that the middle approach has the potential to prohibit productive suits. As an initial matter, the "first-to-file" rule already provides potential relators significant incentive not to sit on the sidelines. As we discuss in more detail below, "a goal behind the first-to-file rule" is to provide incentives to relators to "promptly alert[] the government to the essential facts of a fraudulent scheme." United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1188 (9th Cir. 2001). It is unclear why a relator would wait for a public disclosure and risk another relator bringing suit.

Moreover, the Supreme Court's recent decision in Rockwell, which interpreted the "direct and independent" knowledge requirement of the public disclosure bar, substantially undercuts the conclusion by the D.C. and Sixth Circuits that "little incentive" is necessary for suits brought after a public disclosure. In addressing the meaning of the "direct and independent knowledge" requirement of the "original source" exception in § 3730(e)(4)(B), the Rockwell Court also addressed the meaning of the

term "information" found in both § 3730(e)(4)(A) and § 3730(e)(4)(B). It held that "information" for purposes of both subparagraphs refers to the "information underlying the allegations of the relator's action," not the information underlying the public disclosure. Rockwell, 549 U.S. at 472. The Court noted:

> Section 3730(e)(4)(A) bars actions based on publicly disclosed allegations whether or not the information on which those allegations are based has been made public. It is difficult to understand why Congress would care whether a relator knows about the information underlying a publicly disclosed allegation (e.g., what a confidential source told a newspaper reporter about insolid pondcrete) when the relator has direct and independent knowledge of different information supporting the same allegation (e.g., that a defective process would inevitably lead to insolid pondcrete). Not only would that make little sense, it would raise nettlesome procedural problems, placing courts in the position of comparing the relator's information with the often unknowable information on which the public disclosure was based. Where that latter information has not been disclosed (by reason, for example, of a reporter's desire to protect his source), the relator would presumably be out of court. To bar a relator with direct and independent knowledge of information underlying his allegations just because no one can know what information underlies the similar allegations of some other person simply makes no sense.

Id. at 471-72 (emphasis added).

Rockwell clarifies that the information that the original source has "direct and independent knowledge" of does not have to be the same as the information upon which the public disclosure is based. Thus, a public disclosure concerning governmental fraud resulting from a Huffington Post article may be based on information that is different (to use the example in Rockwell, "what a confidential source told a . . . reporter about insolid pondcrete") than the information a relator may have in support of the same fraud ("that a defective process would inevitably lead to insolid pondcrete"). See id. The same would be true of an ongoing governmental investigation, where the information upon which the government's public disclosures are based may be different from the information that the relator has in his possession.

But as a result of that clarification, Rockwell strongly suggests that situations can arise where the information upon which the public disclosure is based may be unavailable (such as a reporter protecting a source) or be of little value (if based on rumors), while a relator may have different information of the publicly disclosed fraud (such as eyewitness testimony, documents, etc.) of great significance. This has substantial plausibility when the public disclosure is based on the "news media," where sources may fear to come forward to serve as witnesses but others with "direct and independent knowledge" may be so willing. Although in such a situation, the relator, in a technical sense, is not a "true whistleblower," we disagree that such a relator does not "deserve[] any reward that may be obtained by pursuing a qui tam action under the FCA." See

McKenzie, 123 F.3d at 942-43. Thus, the approach taken by D.C. and Sixth Circuits has the potential to bar productive suits.

ii. History

The history of the "public disclosure" bar and the "provided" language under § 3730(e)(4)(B) also does not require us to deviate from the plain meaning. The legislative history of the "public disclosure" bar has been well rehearsed by this and other circuits. See, e.g., Prawer, 24 F.3d at 324-26; see also Findley, 105 F.3d at 679-81. We only discuss legislative history relevant to our inquiry here.

The "provided" language in § 3730(e)(4)(B) was specifically enacted to "'correct[]' the holding of United States ex rel. Wisconsin v. Dean." Findley, 105 F.3d at 691; See also Siller, 21 F.3d at 1354; FMC Corp., 975 F.2d at 1419 ("Seeking only to 'correct' opinions like Dean, Congress permitted one who publicly disclosed the information to bring a qui tam suit."). Dean was a 1984 Seventh Circuit decision decided prior to the 1986 amendments that resulted in the current "public disclosure" bar. The case concerned a previous jurisdictional bar, adopted in 1943, that barred relator suits "'based upon evidence or information in the possession of the United States . . . at the time such suit was brought.'" Findley, 105 F.3d at 680 (omission in original) (quoting Act of December 23, 1943, 57 Stat. 608, recodified in 31 U.S.C. § 3730(b)(4) (1982) (superseded)). The 1943 jurisdictional bar provided no exception for when "the relator was the source of that information," although such an exception was proposed. Id. "In Dean, the Seventh Circuit was faced with the question of whether the State of

Wisconsin should be allowed to act as a qui tam relator in a Medicaid fraud action where the State, in accordance with the federal regulations, had already reported the fraud to the federal court." Prawer, 24 F.3d at 325 (citing United States ex rel. Wisconsin v. Dean, 729 F.2d 1100, 1102-04 (7th Cir. 1984)). The Dean court answered in the negative, stating that "[i]f the State of Wisconsin desires a special exemption to the False Claims Act because of its requirement to report Medicaid fraud to the federal government, then it should ask Congress to provide that exemption." 729 F.2d at 1106.

Congress obliged, and in 1986 Congress amended the FCA to "'encourage more private enforcement suits.'" Findley, 105 F.3d at 680 (quoting S. Rep. No. 93-345, at 23-24 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5288-89); see also Rost, 507 F.3d at 730 (same). As emphasized by the Sixth Circuit, one goal of the amendments was to "prevent 'parasitic' qui tam actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of fraud." McKenzie, 123 F.3d at 943 (quoting Siller, 21 F.3d at 1347).

But two additional changes are relevant here. The first was to abolish the "government knowledge" regime entailed by the 1943 jurisdictional bar, which Congress concluded "proved too restrictive of qui tam actions, resulting in the under-enforcement of the FCA." Rost, 507 F.3d at 729. Congress replaced the "government knowledge" regime with one, as shown by the "public disclosure" bar, focused on the "public disclosure of information given to the government." Id. As put by the D.C. Circuit, "Congress thus changed the focus of the jurisdictional bar from

evidence of fraud inside the government's overcrowded file cabinets to fraud already exposed in the public domain." Findley, 105 F.3d at 684. To replace the "government knowledge" bar, Congress "'broadened the universe of potential [qui tam] plaintiffs, with only four exclusions' enumerated in § 3730(e)." Rost, 507 F.3d at 730 (quoting United States ex rel. LeBlanc v. Raytheon Co., 913 F.3d 17, 19 (1st Cir. 1990)).

The second was to reinstate the "original source" exception proposed, but not adopted, in 1943, so as to avoid the situation in Dean where a potential relator who provided information to the government was not barred from bringing a qui tam suit. It is this second change that the "provided" language sought to remedy, by allowing individuals to maintain suit and "provide their information to the government." As put by the Fourth Circuit:

> To "correct" Dean only required that Congress adopt language that would ensure that a plaintiff who had provided his information to the government would not be barred from bringing a qui tam action on the ground that the government already possessed the information. This it did in section 3730(e)(4)(B), by providing that a plaintiff who produces his independently-obtained information to the government is excepted from section 3730(e)(4)(A)'s jurisdictional bar.

Siller, 21 F.3d at 1354.

The second additional change provides a direct justification of the "provided" language in § 3730(e)(4)(B), but it is the first that has been glossed over. Both the D.C. Circuit and the Sixth

Circuit have focused on the concern with "parasitic" suits, concluding that any such suit brought after a "public disclosure" was necessarily "parasitic." As noted above, we question that conclusion. But we also note that the 1986 amendments equally sought to end a regime that resulted in the "under-enforcement" of the FCA, one that rested too much on government notice to prevent fraud. As we have noted, Congress "amended the statute to 'encourage more private enforcement suits.'" Rost, 507 F.3d at 730 (quoting S. Rep. No. 93-345, at 23-24). Although we have recognized that a "public disclosure" regime has the benefit, one lacking in a "government notice" regime, of providing "public pressure" on the government to act, see Rost, 507 F.3d at 730, there also may arise situations when even that is not enough, and the government would benefit from suits brought by relators with substantial information of government fraud even though the outlines of the fraud are in the public domain.

The D.C. Circuit was quite explicit that its approach "may on occasion prevent qui tam lawsuits that may not be truly 'parasitic.'" Findley, 105 F.3d at 685. However, we have rejected readings of the "public disclosure" bar that "would create a new exclusion not articulated in the text" which would discourage "productive private enforcement." See Rost, 507 F.3d at 730. In Rost, we rejected an interpretation of "public disclosure" under § 3730(e)(4)(A) to include self-disclosures made by a private party only to government agencies without further disclosure, as it would "reinstate exactly what Congress eliminated -- the 'government knowledge' bar." Id. Although the reading urged here would not return us to the "government notice"

regime, it is overbroad so as to prohibit cases that are "productive private enforcement suits." Thus, just as we eschewed reading an exclusion in Rost that did not have textual support and resulted in discouraging "productive private enforcement," we similarly decline to do so here.

We conclude by emphasizing that we are cognizant of our institutional role and the limits of our competence in interpreting the FCA. As noted by the Fourth Circuit, in criticizing the approaches taken by the Second and Ninth Circuit:

> It strikes us as especially inappropriate (not to mention frighteningly treacherous) to attempt, as these courts have done, to distill from such broad, generalized objectives, the answers to the kind of specific statutory questions that we herein address; fine calibrations are just not possible through the use of such crude instruments. This is particularly so in this context, given that, although we can perhaps divine from these abstract purposes a congressional intention to balance the need to encourage qui tam actions against the need to prevent parasitic suits, we can discern virtually nothing as to precisely how Congress ultimately believed it achieved that balance. If the language of law is to have any meaning at all, then surely it must prevail over the kind of speculation that is entailed in such an enterprise as these courts have undertaken.

Siller, 21 F.3d at 1354-55. We agree. The FCA has many moving parts, so that any attempt by us to move one may upset others. Given the difficulty in determining the right "balance," we conclude that

the better approach is to rely upon the plain and unambiguous language of § 3730(e)(4)(B) in the absence of any clear direction to do otherwise.

Thus, we reject OBP's and the government's contention that § 3730(e)(4)(B) requires an "original source" to provide his or her information before the public disclosure at issue. Instead, we will honor the plain and unambiguous terms of the statute, and hold that § 3730(e)(4)(B) only requires that a relator provide his or her information prior to the filing of the qui tam suit.

2. McClellan

The Relators contend that the district court erred in holding that McClellan failed to qualify as an original source. We disagree. As an initial matter, the Amended Complaint alleges that "Relator McClellan does not bring any new legal claims against [OBP], but rather adds additional supporting facts to the legal claims previously made [in the Original Complaint]." (Am. Compl. ¶ 28). Thus, the district court correctly concluded that McClellan was required, in order to qualify as an "original source," to provide his information prior to the filing of the Original Complaint, rather than the Amended Complaint. See Duxbury, 551 F. Supp. 2d at 109.

Although the Amended Complaint alleges that "[b]oth Relators have direct and independent knowledge of information on which the allegations are based, and have provided such information to the United States before filing suit, as required by 31 U.S.C. § 3730(e)(4)," (Am. Compl. 16), the district court noted that Duxbury "proffered no support for this conclusory allegation" and the district court

refused to "reasonably infer it," as "Duxbury did not move to add McClellan as a relator until October 2006." Id. at 110. We agree.

McClellan counters that we are required to "take as true all well-pleaded facts in [the] complaint[]" and "draw all reasonable inferences therefrom in [his] favor." See Fothergill, 566 F.3d at 251. However, we are under no obligation to credit McClellan's conclusory allegations, which simply parrot the elements of the statute. See Rodriguez v. SK & F Co., 833 F.2d 8, 8 (1st Cir. 1987) (per curiam) (affirming dismissal for lack of subject matter jurisdiction where "the plaintiff has failed to allege grounds upon which to support either his conclusory allegation of diversity jurisdiction or federal question jurisdiction."); cf. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (in reviewing a motion to dismiss for failure to state a claim, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

We also refuse to "reasonably infer" McClellan's allegation concerning disclosure. On appeal, McClellan points to a single allegation in the Original Complaint that he "had over 400 Patient Trial Cards in his possession in one time." (Compl. ¶ 39). This allegation does not support an allegation that he provided his information about the kickback claims prior to the filing of the Original Complaint. McClellan also points to the Information, which was provided to the government after the filing of the Original Complaint. The Information provides significant detail concerning the Relators' off-label

promotion claims, not its kickback claims, and thus the Information also provides no support for his allegation that he provided his information prior the filing of the Original Complaint.

For the above reasons, we hold that the district court did not err in holding that McClellan did not qualify as an "original source" under § 3730(d)(1), and thus affirm the dismissal of those kickback claims attributable to McClellan. Accordingly, we do not need to address the district court's alternative ground for dismissing the claim, that those kickback claims attributable to Duxbury are barred by the "first-to-file" rule.

3. Duxbury

We finally address the dismissal of Duxbury claims under Rule 9(b). Duxbury seeks reversal. We agree.

In applying Rule 9(b), the district court held that the rule "requires relators to 'provide details that identify particular false claims for payment that were submitted to the government.'" Duxbury, 551 F. Supp. 2d at 114 (quoting Rost, 507 F.3d at 731) (emphasis added). This was error. In Rost, we noted a distinction between a qui tam action alleging that the defendant made false claims to the government, and a qui tam action in which the defendant induced third parties to file false claims with the government. 507 F.3d at 732 (noting that latter action is "in a different category" than former).[6] In the latter

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[6] Although this distinction resembles the distinction between "subsection (a)(1)" claims, which have a presentment (continued...)

context, we held that a relator could satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility" without necessarily providing details as to each false claim. Rost, 507 F.3d at 733; see also United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009) (holding that FCA claims under Rule 9(b) "may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.").

Similar to this case, Rost concerned allegations that "false claims were allegedly submitted by doctors who were allegedly induced and seduced by defendants into prescribing Genetropin for off-label uses to their patients, including federally insured patients." Id. at 732. We acknowledged that "Rost's complaint amply describes illegal practices in which Pfizer allegedly engaged." Id. However, "[a]s presently pled, the complaint d[id] not sufficiently establish that false claims were submitted for

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requirement, and "subsection (a)(2)" claims, which do not, see Gagne, 565 F.3d at 44-45, our analysis in Rost applied equally to both (a)(1) and (a)(2) claims. See Rost, 507 F.3d at 731-32 (noting that relator there asserted both (a)(1) and (a)(2) claims); see also id. at 733 (rejecting a claim that (a)(2) claims should be treated differently, noting that "[o]ur analysis -- which recognizes the role played by third parties other than Pfizer in submitting claims and making statements to the government -- undermines Rost's § 3729(a)(2) argument as well"). Here, as in Rost, Duxbury asserts both (a)(1) and (a)(2) claims. (See Am. Compl. Count I).

government payment in a way that satisfies the particularity requirement." Id. at 733. We noted:

> It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. Rost did not plead enough to satisfy the concerns behind Rule 9(b).

Id.

Here, as in Rost, Duxbury does not allege that OBP itself submitted false claims to the government, but that, through OBP's illegal kickbacks, false claims to the Medicare Program were filed by medical providers for reimbursement of Procrit purchases. However, unlike in Rost, Duxbury does more than "suggest fraud was possible." Id. at 733. Duxbury sets forth allegations of kickbacks provided by OBP that resulted in the submission of false claims by eight healthcare providers in the Western United States: (1) St. Joseph's Hospital in Tacoma, Washington (Am. Compl. ¶ 211a); (2) Rainier Oncology of Puyallap, Washington (Am. Compl. ¶ 211b); (3) Memorial Clinic in Olympia, Washington (Am. Compl. ¶ 211c); (4) Western Washington Cancer Treatment Center (Am. Compl. ¶ 211d); (5) Mid Columbia Kidney Center in Kennewick, Washington (Am. Compl. ¶ 211e); (6) St. Peter's Hospital in Olympia, Washington (Am. Compl. ¶ 211f); (7) Memorial Clinic Oncology Group in

Washington (Am. Compl. ¶ 211g); (8) Swedish Hospital in Seattle, Washington (Am. Compl. ¶ 211h). As to each, Duxbury provides information as to the dates and amounts of the false claims filed by these providers with the Medicare program. One such allegation is instructive:

> In 1997-98 Western Washington Treatment Center in Olympia, Washington received more than $5,000 of free commercially packaged ProCrit from [OBP] under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. [OBP] intended the free commercially packaged ProCrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase ProCrit and to administer ProCrit at the "off-label" once a week dosing regimen. Western Washington was reimbursed by Medicare for the free commercially packaged ProCrit. As a result, [OBP] knowingly caused the presentation by Western Washington of these false claims to the United States Government.

(Am. Compl. ¶ 211d). Duxbury provides more specifics with respect to other medical providers. As to St. Joseph's Hospital, Duxbury alleges that the hospital submitted "approximately 4,800 claims a month for Medicare reimbursement" based upon OBP's unlawful kickbacks. (Am. Compl. ¶ 211a).

Although a close call, Duxbury's claims satisfy Rule 9(b) under this "more flexible standard." See

Gagne, 565 F.3d at 46. Although Duxbury does not identify specific claims, he has alleged the submission of false claims across a large cross-section of providers that alleges the "the who, what, where, and when of the allegedly false or fraudulent representation." See Rodi v. So. New England Sch. of Law, 389 F.3d 5, 15 (1st Cir. 2004) (quotation omitted); see also Rost, 507 F.3d at 731 (noting that Rule 9(b) requires a plaintiff to allege "'the time, place, and content of an alleged false representation.'" (quoting Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996))). In particular, Duxbury has identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves.

Moreover, as to his (a)(2) claims, Duxbury has also alleged facts with respect to the medical providers he identifies that support his claim that OBP intended to cause the submission of false claims. See Allison Engine, 128 S. Ct. at 2126 (holding that an action under subsection (a)(2) requires a relater to allege "that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim"); see also Gagne, 565 F.3d at 47 (affirming dismissal of an (a)(2) claim under Rule 9(b) where "[r]elators fail to connect the only falsity or fraud for which they provide any detail").

With respect to Western Washington, Duxbury alleges that "Washington received more than $5,000 of free commercially packaged ProCrit from [OBP] . . . so that Western Washington could submit the free product for reimbursement to Medicare under

the false and fraudulent certification that the provider had paid for the product," and that "Western Washington was reimbursed by Medicare for the free commercially packaged ProCrit." (Am. Compl. ¶ 211d) (emphasis added). The same is true of the other medical providers. See, e.g., id. 211a ("[OBP] intentionally failed to report these payments to the US Government in order to keep secret the profit spread between the rate upon which Medicare reimbursed medical providers like St. Joseph's for ProCrit."); id. ¶ 211b ("Ranier Oncology . . . was provided more than $20,000 of free commercially packaged ProCrit from [OBP] . . . under the guise of running an unlawful mini-trial so that Rainier Oncology could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product."); id. ¶ 211c ("Memorial Clinic . . . was provided approximately $15,000 of free commercially packaged ProCrit from [OBP] so that Memorial Clinic could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product."); id. ¶ 211e ("Mid Columbia Kidney Center . . . submitted claims to Medicare and was subsequently reimbursed by Medicare approximately $75,000 for the administering of ProCrit to Mid Columbia Kidney Center patients. . . . [OBP] provided Mid Columbia Kidney Center with an 'off-invoice' rebate of 5-8% for the purchase of ProCrit. [OBP] intentionally failed to report those 'off-invoice' rebates in order to keep secret the 'profit spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211f ("St. Peter's Hospital . . . submitted claims to

Medicare for approximately two million dollars of ProCrit. St. Peter's contract with [OBP] provided St. Peter's with an 'off-invoice' rebate of 14% for the purchase of ProCrit. [OBP] intentionally failed to report to the U.S. Government these 'off-label' rebates in order to keep secret the 'profit spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211g ("Memorial Clinic Oncology Group . . . purchased $750,000 of ProCrit. Memorial Clinic Oncology Group's agreement with [OBP] provided Memorial Clinic Oncology Group with an 'off-invoice' rebate of 5% for the purchase of ProCrit. [OBP] intentionally failed to report to the US Government the 'off-invoice' rebates in order to keep the 'profit-spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211h ("Swedish Hospital . . . was given cash in the form of a so-called 'unrestricted educational grant' in the amount of approximately $15,000 [which was a kickback]. Provider subsequently purchased over $100,000 of ProCrit of which approximately 50% was submitted for Medicare reimbursement.").

Unlike in Rost, where the allegations gave rise to only speculation as to whether the alleged scheme caused the filing of false claims with the government, Duxbury has alleged facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide. We thus have allegations of "factual . . . evidence to strengthen the inference of fraud beyond possibility." Rost, 507 F.3d at 733.

Although we find that the factual evidence alleged here of the submission of false claims caused by OBP at a cross-section of medical providers, is sufficient in this context, "[w]e decline to draft a litigation manual full of scenarios" of what allegations would be sufficient for purposes of Rule 9(b). LeBlanc, 913 F.2d at 20 (discussing "original source" exception). "Suffice it to say that we limit our holding to the facts." Id. Accordingly, we conclude that Duxbury's allegations pass muster for purposes of Rule 9(b).

Thus, we hold that the kickback claims attributable to Duxbury, from the years 1992 through 1998, satisfied Rule 9(b). As the district court has jurisdiction over these claims since Duxbury established himself as an "original source," we reverse the dismissal of these claims.[7]

B. Count III

The Relators contend that the district court erred in dismissing the "off-label" promotion claims contained in Count III. The district court relied upon

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[7] OBP urges other alternative grounds for affirming the dismissal of the Duxbury kickback claims. We deal with them briefly. OBP first claims the statute of limitations bars most of Duxbury's kickback claims. As the district court has not addressed the issue, we leave it to the district court to address it in the first instance. OBP also argues that the district court abused its discretion in permitting Duxbury to serve the Original Complaint outside the 120-month window mandated by Federal Rule of Civil Procedure 4(m) and D. Mass. Local Rule 4.1(b). We identify no abuse of discretion.

the "first-to-file" bar, which provides that "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The Blair Complaint, filed nearly a year before the Amended Complaint, also alleged a similar "off-label" promotion claim. Accordingly, the district court examined whether the Original Complaint, filed a month before the Blair Complaint, sufficiently alleged an "off-label" claim to be considered the first-filed complaint for purposes of the "first-to-file" bar. Duxbury, 551 F. Supp. 2d at 110-11. After carefully considering the allegations contained in both complaints, the district court concluded that, despite some similarities, the Original Complaint did "not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit." Id. at 114 (emphasis added). We agree.

As the Ninth Circuit has noted, "a goal behind the first-to-file rule" is to provide incentives to relators to "promptly alert[] the government to the essential facts of a fraudulent scheme." Lujan, 243 F.3d at 1188. All courts that have addressed the issue have interpreted § 3730(b)(5) to bar "a later allegation [if it] states all the essential facts of a previously-filed claim" or "the same elements of a fraud described in an earlier suit." United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232-33 (3d Cir. 1998) (emphasis added); see also United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 217-18 (D.C. Cir. 2003) (holding that "§ 3730(b)(5) bars any action incorporating the same material elements of fraud as an action filed earlier" and "reject[ing] another possible test, one barring claims based on 'identical

facts.'"); Lujan, 243 F.3d at 1188-89 (following LaCorte, and rejecting an "identical facts" test). Under this "essential facts" standard, § 3730(b)(5) can still bar a later claim "even if that claim incorporates somewhat different details." LaCorte, 149 F.3d at 232-33. We take the same approach.

The Relators contend that the Original Complaint, in particular, Paragraphs 40 through 42, allege all of the "essential facts" of the off-label promotion scheme. As the district court found, there are significant similarities between the "off-label" promotion allegations contained in those paragraphs and the allegations in the Blair Complaint. Both allege that OBP did not have FDA approval for "a dosing regimen of 40,000 units once per week." (Compare Original Compl. ¶¶ 40(c), 41; Blair Compl. ¶¶ 22-27). Both allege that OBP promoted this dosage in order to "increase . . . payments for each Medicare Beneficiary receiving Procrit for treatment." (See Original Compl. ¶¶ 40(c), 41; Blair Compl. ¶¶ 22-27). And both allege that the higher dosage resulted in the filing of false claims with the government. See Duxbury, 551 F. Supp. 2d at 113 (noting these similarities).

However, the Original Complaint and Blair Complaint differ in one crucial respect. As recognized by the district court, the Blair Complaint contained a number of allegations that discuss, in significant detail, OBP's promotion of the "off-label" use, and alleged such "promotion" efforts as

> (1) direct off-label marketing to medical professionals; (2) influencing the results of purportedly independent clinical studies; (3) illegal payments to medical professionals in

> the form of "educational grants" and "clerkships;" (4) payments to medical professionals for giving presentations on increased dosage of Procrit; or (5) attending consulting conferences sponsored by OBP which pushed increased dosage of Procrit; and (6) rebate programs offered to induce increased prescriptions of Procrit.

Id. at 113 (citing Blair Compl. ¶¶ 27, 28-79). By contrast, Paragraphs 40 through 42 of the Original Complaint only allege one method by which OBP promoted the "off-label" use of Procrit, the use of "clinical trials," and, in particular, an unnamed "Phase IV Study" that "resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week -- an increase in 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia." (Compl. ¶ 40(c)). As this allegation fails to encompass the other allegations contained in the Blair Complaint concerning OBP's "off-label" promotion, it fails to allege the "essential facts" of the "off-label" promotion scheme contained in the Blair Complaint. In fact, the Original Complaint nowhere refers to a "off-label" promotion scheme. Thus, we conclude that the Original Complaint cannot trump the Blair Complaint for purposes of the "first-to-file" rule.

On appeal, the Relators argue that the Information, which the Relators provided to the DOJ in response to its inquiries concerning the allegations contained in the Original Complaint, provided further allegations that covered the "essential facts" contained in the Blair Complaint. We have previously held that, in reviewing a dismissal for

lack of jurisdiction, "we need not confine our jurisdictional inquiry to the pleadings, but may consider those other materials" in the district court record. Aguilar, 510 F.3d at 8. We decline to do so here. The "first-to-file" rule is "exception-free," Lujan, 243 F.3d at 1187, and does not permit us to consider the Information, which was provided after the filing of the Blair Complaint.[8] Had Duxbury wanted to include the allegations contained in the Information, he had his opportunity to do so when he filed the Original Complaint seven months earlier.

For the above reasons, the district court did not err in dismissing Count III.

III. Conclusion

For the foregoing reasons, we affirm the dismissal of all claims except those kickback claims attributable to Duxbury. For these latter claims, we reverse the dismissal and remand for further proceedings consistent with this opinion.

Affirmed in part, Reversed in part and Remanded.

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[8] We also note that the Information was produced after the Blair Complaint was made available to the Relator Duxbury, although the Relators contend that Duxbury had not yet received the Information.

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 03-12189-RWZ

UNITED STATES OF AMERICA *ex rel.*
MARK EUGENE DUXBURY and DEAN
McCLELLAN

v.

ORTHO BIOTECH PRODUCTS, L.P.

MEMORANDUM OF DECISION AND ORDER

January 28, 2008

ZOBEL, D.J.

Relators Mark Duxbury ("Duxbury") and Dean McClellan ("McClellan") (collectively, "Relators") have filed this action against defendant Ortho Biotech Products, L.P. ("OBP") under the qui tam provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3730, which permits a private person to file an action on behalf of the United States. The case is before me on defendant's motion to dismiss. For the reasons discussed below, the motion is allowed.

I. Procedural History

Duxbury originally filed this action in November 2003. The FCA requires that the relator file his action under seal, during which time the United

States may investigate and evaluate the allegations and determine whether to intervene in the action. 31 U.S.C. § 3730(b)(2). On July 12, 2005, the United States gave notice of its declination to intervene, and the court ordered Duxbury to serve defendant. After a succession of requests for extensions, defendant was served on October 12, 2006. Duxbury subsequently moved to amend the complaint as of right and add McClellan as a co-relator pursuant to Federal Rule of Civil Procedure 15(a). This court allowed the motion over defendant's objection, noting that defendant had not yet filed a responsive pleading, and although the amended complaint increased in size, it was "less clear that the proposed amendment adds entirely new violations" of the FCA. (Docket # 50, 2.) The amended complaint explicitly states:

> Relator Duxbury is the original source of the claims and allegations contained in the original Complaint and the Amended Complaint. Through the course of his investigation Relator Duxbury developed Relator McClellan as an additional Relator. Relator McClellan is an additional relator who provides additional supporting facts and information. Relator McClellan does not bring any new legal claims against Defendant, but rather adds additional supporting facts to the legal claims previously made.

(First Amended Complaint ("Am. Compl.") (Docket # 51-3) ¶ 28.) Defendant has moved to dismiss the amended complaint, arguing, inter alia, that this court lacks jurisdiction over the suit and that Relators have not pled their claims with the requisite particularity.

II. Factual Background

A. The FCA

The FCA prohibits false or fraudulent claims for payment to the federal government and permits civil actions based on such claims to be brought by the Attorney General or by private individuals acting in the government's name. 31 U.S.C. § 3730(a)-(b). When the individual brings a suit in the government's name, the individual is known as the "relator," and his action is a "qui tam" suit.[1] The FCA does not create a cause of action against all fraudulent conduct affecting the government. Rather, FCA liability attaches to a "false or fraudulent claim for payment" or to a "false record or statement [made] to get a false or fraudulent claim paid" by the government. 31 U.S.C. § 3729(a)(1)-(2); United States ex rel. Rost v. Pfizer. Inc., 507 F.3d 720, 727 (1st Cir. 2007).

The statute further limits the actions that may be brought in several ways, two of which are relevant for present purposes. First, when a private individual brings an FCA action, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). This so-called "first-to-file" rule operates to prevent

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[1] "Qui tam" is shorthand for "qui tam pro domino rege quam pro se ipso in hac parte seguitir," meaning "who pursues this action on our Lord the King's behalf as well as his own." Rockwell Int'l Corp. v. United States, --- U.S. ---, 127 S. Ct. 1397, 1403 n.2 (2007).

multiplication of FCA suits that could lead to duplicative awards covering the same behavior. United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 233-34 (3d Cir. 1998). Second, under the "public disclosure" bar, the court does not have jurisdiction over a private individual's action if his claims are "based upon" the "public disclosure" of allegations or transactions, unless the individual bringing the suit is an "original source" of the information. 31 U.S.C. § 3730(e)(4).[2]

The FCA's jurisdictional scheme serves two competing purposes. On one hand, it seeks "to inspire whistleblowers to come forward promptly with information concerning fraud so that the

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[2] The relevant provision states in total:

> (4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4).

government can stop it and recover ill-gotten gains." United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 685 (D.C. Cir. 1997). On the other hand, it attempts to discourage so-called "parasitic" suits, in which opportunistic plaintiffs sue based upon information already publicly disclosed or that they did not otherwise discover. United States ex rel. S. Prawer and Co. v. Fleet Bank of Maine, 24 F.3d 320, 326 (1st Cir. 1994). The FCA's qui tam provisions must be analyzed in the context of these twin goals. Id.

B. Relators and Their Claims[3]

Relator Duxbury was employed by defendant from 1992 to 1998, beginning as a Product Specialist and eventually becoming a Regional Key Account Specialist for OBP's Western Division Oncology sales force. Relator McClellan was employed by defendant from 1992 to 2004, beginning as a Product Specialist and eventually becoming a Territory Manager for OBP's Western Division Oncology sales force. In their positions, Relators were "responsible for the promotion and sale of [OBP's drug Procrit®[4]] for Defendant in the Western United States." (Am. Compl. ¶ 17.)

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[3] This subsection is drawn from allegations contained in Relators' First Amended Complaint (Docket # 51-3).

[4] Procrit® ("Procrit") is the brand name for epoetin alfa, a drug which is marketed by OBP and used to treat anemia caused by chemotherapy, chronic kidney disease, HIV infection, and blood loss from certain types of surgery.

The amended complaint alleges three separate violations of the FCA. First, Relators allege that beginning in 1992, OBP undertook a scheme to give kickbacks to providers and hospitals to induce them to prescribe Procrit. The kickbacks allegedly included free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria. (Am. Compl. ¶ 228.) Relators allege that the kickbacks caused providers and hospitals to submit false claims for payment to Medicare. They claim that the time period of the false claims is from "December 1992 to the present." (Id. ¶ 232.)

Second, Relators allege that defendant engaged in a scheme to publish inflated "Average Wholesale Prices" for Procrit that did not represent a real average of the wholesale prices for the drug. The parties have jointly stipulated to the dismissal of this claim (see Docket # 79), and the court will not consider it further.

Third, Relators allege that defendant promoted off-label dosing of Procrit in violation of the Food, Drug and Cosmetic Act and used "sham drug trials" to falsify eligibility for Medicare reimbursement for off-label uses of the drug. (Am. Compl. ¶ 271.) Relators claim that the time period for this claim is from January 1998 to the present. (Id. ¶ 273.)

Defendants move to dismiss the First Amended Complaint in its entirety on the grounds that the court lacks jurisdiction under the FCA's public disclosure bar, that certain claims are barred by the "first-to-file" rule, and that plaintiffs have not pled fraud with the requisite particularity. Additionally,

defendants assert that the "off-label" claims fail to state violations of the FCA.

III. Subject Matter Jurisdiction

A qui tam relator's qualification to bring a suit is an issue of subject matter jurisdiction. Rockwell Int'l Corp. v. United States, --- U.S. ---, 127 S. Ct. 1397, 1405-06 (2007). Jurisdiction is based upon Relators' amended complaint. Id. at 1409. Plaintiffs bear the burden of establishing that the court has jurisdiction to hear their claims. Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995). The court treats all well-pleaded facts as true and indulges all reasonable inferences in favor of the plaintiff. Aversa v. United States, 99 F.3d 1200, 1210 (1st Cir. 1996). "In addition, the court may consider whatever evidence has been submitted, such as depositions and exhibits . . . ." Id. Statutes such as the FCA which confer jurisdiction on federal courts "are to be strictly construed, and doubts resolved against federal jurisdiction." United States ex rel. Precision Co. v. Koch Indus., Inc., 971 F.2d 548, 552 (10th Cir. 1992).

The FCA does not permit "jurisdiction in gross." Rockwell, 127 S. Ct. at 1410. Instead, the court must examine Relators' ability to assert each claim. Id. ("The plaintiff's decision to join all of his or her claims in a single lawsuit should not rescue claims that would have been doomed by section (e)(4) if they had been asserted in a separate action. And likewise, this joinder should not result in the dismissal of claims that would have otherwise survived." (quoting United States ex rel. Merena v. SmithKline Beecham Corp., 205 F.3d 97, 102 (3d Cir.

2000) (Alito, J.))). Accordingly, I will analyze the two remaining claims individually.

A. Count I: Kickbacks

Count I alleges a scheme to give kickbacks in the form of free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria to providers and hospitals to induce them to prescribe Procrit. The parties disagree regarding whether the public disclosure bar prohibits this claim.

The FCA prohibits qui tam actions when the relator's allegations are "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media . . . ." 31 U.S.C. § 3730(e)(4)(A). The jurisdictional inquiry under Section 3730(e)(4) proceeds in three steps. The court must determine: (1) whether the allegations or transactions have been publicly disclosed in a manner provided by the statute; (2) if so, whether the relator's suit is "based upon" those allegations or transactions; and (3) if the answer to both questions is yes, whether the relator falls within the "original source" exception to the jurisdictional bar. United States ex rel. O'Keefe v. Sverdup Corp., 131 F. Supp. 2d 87, 91 (D. Mass. 2001).

1. Public Disclosure

The widely accepted framework for determining whether a public disclosure of the qui tam complaint's allegations or transactions has occurred is set forth in United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654-55 (D.C. Cir. 1994). As the court in Quinn explained, "if X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements." Id. at 654. A public disclosure has occurred when either: (1) an allegation of fraud has been made (Z); or (2) both of the "essential elements" of the fraud – "a misrepresented state of facts and a true state of facts" (X and Y) – are in the public domain. Id. at 655.

OBP asserts that the essential elements supporting Count I were publicly disclosed in prior civil litigation and various government and media reports prior to Duxbury filing his initial complaint in November 2003.[5] Although the First Circuit has not addressed the issue, "every court of appeal to have addressed the question has held that any information disclosed through civil litigation and on file with the clerk's office should be considered a

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[5] OBP does not suggest that the court consider public disclosures made during the period between the initial and amended complaints. See United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr., No. 4:05-CV-00899, 2007 WL 2904111, at *8 (E.D. Ark. Sept. 28, 2007). However, because the public disclosures made prior to the filing of Duxbury's initial complaint are sufficient it is not necessary to consider subsequent disclosures.

public disclosure . . . for purposes of section 3730(e)(4)(A)." United States v. Northrop Corp., 59 F.3d 953, 966 (9th Cir. 1995) (quoting United States ex rel Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1350 (4th Cir. 1994) (collecting cases)); see also Walburn v. Lockheed Martin Corp., 431 F.3d 966, 974 (6th Cir. 2005); Quinn, 14 F.3d at 652.

The prior litigation in this instance is a multi-district litigation termed In re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, Civ. No. 01-12257-PBS ("AWP MDL"), currently pending in this District. The AWP MDL includes both private class action suits and suits on behalf of various States and other Medicare and Medicaid payors against a large number of pharmaceutical manufacturers. Plaintiffs in the AWP MDL filed a Master Consolidated Class Action Complaint ("MCC") in September 2002, more than a year before Duxbury filed his qui tam complaint in November 2003. (MCC (AWP MDL Docket # 148), Sept. 6, 2002.)) The MCC alleged that OBP and its co-defendants engaged in widespread fraudulent conduct, including kickbacks, improper use of free samples, discounts, rebates and "other hidden and improper inducements and price reductions." (See MCC ¶¶ 108-09, 131, 153, 162-172, 294-98.)

Relators argue that the MCC did not publicly disclose OBP's alleged fraud because (1) "it only revealed the component of Ortho's scheme that involved consumers, insurers and third party payers but not the manipulation of the Medicare reimbursement system," and (2) "it did not contain elements of the scheme of having Ortho's sales force intentionally cause the submission of false claims to the Government." (Relators' Mem. in Opp. to Def.'s

Mot. to Dismiss (Docket # 65), 20.) These arguments are strained, to say the least. Allegations regarding reimbursement by Medicare Part B based upon published Average Wholesale Prices ("AWPs") are a central component of the MCC, to the point that the MCC expends numerous paragraphs describing the Medicare insurance and reimbursement system and the impact of allegedly inflated AWPs on this system. (See, e.g., MCC ¶¶ 3-4, 133, 140-165.) Moreover, the "AWP Scheme" alleged in the MCC, in which pharmaceutical companies "marketed the spread" to providers to induce them to prescribe drugs based upon the "profit" generated by receiving reimbursements from Medicare which were higher than their actual costs,[6] has at its very root the

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[6] The AWP MDL court summarized the plaintiffs allegations:

> The pharmaceutical companies vastly overstate the AWPs of many drugs . . . .
>
> This overstatement in the reporting creates a "spread" . . . between the actual cost of a drug to a health care provider, and the reimbursement paid to the provider by the federal government. . . . Defendants actively market this "spread" to providers, who are encouraged to buy drugs from defendants at the highly "discounted" actual prices, and are urged to keep the reimbursement and co-payment spreads for themselves. . . .
>
> For some defendants, the AWP scheme is not the only mechanism used to create the artificial "spreads." Another method involves the provision of "free samples" to health providers who are sometimes encouraged to bill their customers for the samples as they would any

(continued...)

submission of false claims to the government. (See id. ¶¶ 139, 157-165; see also id. ¶ 171 ("Defendant Drug Manufacturers incentivize [*sic*] providers under Medicare Part B to use (and submit reimbursement claims for) the drugs with the highest-inflated AWP. . . ."). The MCC's allegations of kickbacks and other fraudulent inducements made by OBP and its codefendants to providers more than adequately "set government investigators on the trail of fraud." Quinn, 14 F.3d at 655.[7]

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other drug. This "free sample" scheme lowers the providers' overall costs while not reducing the amount they receive in reimbursements from the federal government, or co-payments from consumers, which remain tied to the reported AWPs. Other fraudulent pricing practices include off-invoice pricing, phony consulting fees, as well as debt forgiveness, rebates, and grants. All of these incentives were designed to lower the providers' net cost of purchasing the drugs.

In re Pharm. Indus. Avg. Wholesale Price Litig., 263 F. Supp. 2d 172, 178-79 (D. Mass. 2003). The court issued this opinion in May 2003, nearly six months prior to Duxbury's initial complaint.

[7] The government argues that its prior reports do not constitute public disclosures because they did not contain either the allegation of fraud or both of the essential elements of fraud. (See United States' Statement of Interest in Resp. to Def.'s Mot. to Dismiss Compl. (Docket # 63), 4-6.) Because the MCC constitutes sufficient public disclosure of the alleged fraud, I do not consider whether the government reports also qualify.

2. Based Upon

Courts do not uniformly agree about the standard for judging whether an action is "based upon" a public disclosure, and the First Circuit has not yet spoken on the issue. Within the District of Massachusetts, four judges have considered the issue. Three have adopted the "minority rule," which says that an action is "based upon" a public disclosure "only when the allegations supporting the action are 'derived from' the public disclosure." E.g., United States ex rel. Rost v. Pfizer, Inc., 446 F.Supp.2d 6, 19 (D. Mass. 2006) (discussing cases and adopting minority view), vacated on other grounds, Rost, 507 F.3d at 734. One judge has adopted the "majority rule," which states that an action is "based upon" a public disclosure "when the supporting allegations are similar to or the same as those that have been publicly disclosed . . . regardless of where the relator obtained his information." O'Keeffe, 131 F. Supp. 2d at 92 (internal quotation marks, citation and emphasis omitted) (adopting majority view).

I adopt the majority view, which I believe better comports with both the policies underlying the provision and the Supreme Court's recent Rockwell decision. In Rockwell the Court held that the "information" in §§ 3730(e)(4)(A) and (B) is the information underlying the allegations in the relator's action, not the information underlying the

publicly disclosed allegations.[8] 127 S. Ct. at 1407-08. The Court reasoned:

> It is difficult to understand why Congress would care whether a relator knows about the information underlying a publicly disclosed allegation (e.g., what a confidential source told a newspaper reporter about insolid pondcrete) when the relator has direct and independent knowledge of different information supporting the same allegation (e.g., that a defective process would inevitably lead to insolid pondcrete). Not only would that make little sense, it would raise nettlesome procedural problems, placing courts in the position of comparing the relator's information with the often unknowable information on which the public disclosure was based. Where that latter information has not been disclosed (by reason, for example, of a reporter's desire to protect his source), the relator would presumably be out of court. To bar a relator with direct and independent knowledge of information underlying his allegations just because no one can know what information underlies the similar allegations of some other person simply makes no sense.

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[8] As discussed more fully infra, if a qui tam suit is based upon public disclosure, the court lacks jurisdiction unless the relator is an "original source of the information." To be an "original source" the relator must, inter alia, have "direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. §§ 3730(e)(4)(A), (B).

Id. Under the minority view, the Court's exemplar relator – one with "direct and independent knowledge of different information supporting the same allegation" – would not fall into the public disclosure bar at all because his allegations would not be "derived from" the public disclosure. However, the Court's discussion presupposes that a relator's allegation which is similar to or the same as the publicly disclosed allegation is subject to the public disclosure bar and must show that he has direct and independent knowledge of the information underlying his allegations.

In the same vein, other courts have noted that the minority view's narrow reading of "based upon" renders the original source exception superfluous. The minority view, which would not find a qui tam action "based upon" the public disclosure so long as the relator possesses independent knowledge of the allegations, "swallows the original source exception whole." Findley, 105 F.3d at 684; accord United States ex rel. Biddle v. Bd. of Trs. of Leland Stanford, Jr. Univ., 161 F.3d 533, 538 (9th Cir. 1998); United States ex rel. Mistick PBT v. Housing Auth. of the City of Pittsburgh, 186 F.3d at 386-87 (3d Cir. 1999).

Additionally, a broader interpretation of "based upon" is more consistent with the policies underlying the public disclosure bar. O'Keefe, 131 F. Supp. 2d at 93 (minority view "would contravene the congressional policy of prohibiting qui tam actions where the government has sufficient information to pursue the false claim itself" (citing Findley, 105 F.3d at 685)).

As the kickback allegations in the Amended Complaint are the same as those alleged in the MCC, the conclusion is inescapable that Relators' claims are based upon the public disclosures.

3. Original Source Exception

Given the public disclosures, Relators may only maintain this action if they qualify as "original sources" for the kickback allegations. 31 U.S.C. § 3730(e)(4)(A). An "original source" is defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." Id. § 3730(e)(4)(B).

On this issue, too, the Supreme Court recently provided guidance in Rockwell. The Court first emphasized that the "original source" inquiry is an issue of subject matter jurisdiction. 127 S. Ct. at 1406. It then determined that "the 'information' to which subparagraph [3730(e)(4)](B) speaks is the information upon which the relators' allegations are based," meaning that the inquiry should not focus on whether the relator was the source of the public disclosure, but rather whether he is an original source of the information underlying his own suit. Id. at 1407-08. Finally, the Court held that the term "allegations" in the phrase "information on which the allegations are based" is not limited to the allegations of the original complaint, but "includes (at a minimum) the allegations in the original complaint as amended." Id. at 1408 (emphasis in original).

a. Duxbury

OBP asserts that Duxbury cannot qualify as an original source because he did not provide the government with his information prior to the public disclosure. Duxbury denies that this is a requirement under the statute. Courts have split on this issue.[9] See Rost, 446 F. Supp. 2d at 22-23 (discussing cases). The plain language of the FCA only requires the relator to provide his information to the government prior to filing his action. See § 3730(e)(4)(B). This unambiguous statutory language must guide the court's interpretation. Lamie v. United States, 540 U.S. 526, 534 (2004); cf. Rost, 507 F.3d at 730 (rejecting an interpretation of the FCA that would "create a new exclusion not articulated in the text"). Accordingly, to be an original source, a relator must: "(1) have independent knowledge of the fraud alleged in his complaint; (2) have direct knowledge of that fraud; and (3) have disclosed this information to the government before filing suit," Rost, 446 F. Supp. 2d at 24, but need not have disclosed the information to the government prior to the public disclosure.

"A relator's knowledge is 'direct' if she acquired it through her own efforts without an intervening agency, and it is 'independent' if her knowledge is not dependent on the public disclosure." O'Keefe, 131 F. Supp. 2d at 93 (citing Quinn, 14 F.3d at 656).

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[9] The Supreme Court did not grapple with this issue in Rockwell, as the relator in that case provided the information to the government prior to the public disclosure. See Rockwell, 127 S. Ct. at 1402.

In his position as a Product Specialist and later Regional Key Account Specialist for OBP's Western Division Oncology sales force, Duxbury was responsible for the promotion and sale of Procrit in the western United States. The complaint alleges that, at defendant's direction, he gave providers free samples of Procrit and instructed the providers to submit Medicare claims for the samples, see, e.g., Am. Compl. ¶¶ 91-93, 99-100, and directly provided discounts, rebates, educational grants, and other "off-invoice" discounts to providers to lower the actual acquisition cost of Procrit, see id. ¶¶ 106-109. His knowledge of the alleged fraud is both independent and direct. Duxbury also alleged in his initial complaint instigating the action that he had provided the information to the government prior to filing the suit. (See Compl. ¶ 9.)

Duxbury therefore qualifies as an original source. However, his direct knowledge of OBP's activities only extends to the time he was employed by the company. He has no direct knowledge of OBP activities occurring after he was terminated in 1998. Therefore, he qualifies as an original source only with regard to allegations concerning the 1992-1998 time period. See Rockwell, 127 S. Ct. at 1409-10.

b. McClellan

McClellan does not qualify as an original source. By the express terms of the statute, he would only qualify if he "voluntarily provided the information to the Government before filing an action" based on the information. § 3730(e)(4)(B). Here, McClellan does not assert any new claims of his own, but only "adds additional supporting facts to the legal claims previously made." (Am. Compl. ¶ 28.) He therefore

must show that he provided the information to the government prior to the claims being made, i.e., prior to Duxbury filing suit in November 2003. Although McClellan claims to have "provided such information to the United States before filing suit," Am, Compl. ¶ 16, Relators have proffered no support for this conclusory assertion, and given that Duxbury did not move to add McClellan as a relator until October 2006, the court cannot reasonably infer it. Murphy, 45 F.3d at 522 (party invoking jurisdiction "carries the burden of proving its existence" and "may not rest merely on unsupported conclusions") (internal quotation marks and citations omitted).[10] See also United States ex rel. McBride v. Halliburton Co., Civ. A. No. 05-00828, 2007 WL 1954441, at *3-*4 (D.D.C. July 5, 2007); United States ex rel. Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 51 n.14 (D.D.C. 2007) ("Rockwell[] . . . strongly indicate[s] that each party who wishes to bring a qui tam suit must be able to invoke the court's jurisdiction. To do otherwise would permit the kind of 'claim smuggling' – or in this case, party smuggling – that Rockwell forbids.").[11]

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[10] As discussed supra, the conclusory assertion suffices for Duxbury because it was made in his initial complaint instigating the action. However, there is no indication that McClellan gave his information to the government prior to Duxbury filing suit.

[11] Relators filed an "Offer of Proof' with regard to providing information to the government relating to their third claim for "off-label" marketing. (Docket # 78.) As the Offer consists of a June 2004 letter to the government, it does not support the (continued...)

Even if he qualified as an original source, McClellan would be barred by the "first-to-file" bar. As discussed more fully infra, the first-to-file bar in § 3730(b)(5) prevents private plaintiffs "from bringing related actions based on the same underlying facts." United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187 (9th Cir. 2001). The first-to-file bar is "exception-free," id., and cannot be circumvented simply by amending the complaint to add McClellan as a relator when his claims would have been barred had they been brought on their own. United States ex rel. Fry v. Guidant Corp., Civ. A. No. 3:03-0842, 2006 WL 1102397, *6 (M.D, Tenn. Apr. 25, 2006); see also Fed. Recovery Servs., Inc. v. United States, 72 F.3d 447, 453 (5th Cir. 1995); LaCorte, 185 F.3d at 191.

B. Count III: Off-Label Marketing[12]

OBP argues that both the first-to-file bar and the public disclosure bar preclude this court from exercising jurisdiction over Relators' off-label marketing claim. Because the former does bar the claim, I do not consider the latter.

Section 3730(b)(5)'s "first-to-file" rule provides: "When a person brings an [FCA qui tam] action . . . no person other than the Government may intervene

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assertion that McClellan provided the government with the information prior to November 2003.

[12] "Off-label marking" refers to the promotion of a product for a use not approved by the Food and Drug Administration ("FDA").

or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The first-to-file bar furthers the policy of the FCA in that "[t]he first-filed claim provides the government notice of their essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims." Lujan, 243 F.3d at 1187 (citing LaCorte, 149 F.3d at 232).

Duxbury filed his original complaint in November 2003 ("Duxbury Complaint") (Docket # 1). In December 2003, a separate relator, Kurt Blair ("Blair") filed a qui tam complaint in the District of Colorado which alleged a scheme by OBP to market off-label uses of Procrit. See United States ex rel. Blair v. Ortho Biotech, Inc., Civ. No. 03-02585 (D. Colo. Dec. 22, 2003) ("Blair Complaint") (Docket # 59). The Blair Complaint was unsealed in November 2005, nearly a year before the First Amended Complaint was filed in this action in October 2006. OBP asserts that the Duxbury Complaint did not include the amended complaint's allegations regarding off-label marketing, and those allegations are therefore barred under the first-to-file rule because of the Blair Complaint. Plaintiffs counter that the Duxbury Complaint contained sufficient allegations of off-label marketing by OBP, such that the Blair Complaint was not filed "first" and does not act as a bar to the claim.

1. Legal Standard

Although the First Circuit has not yet spoken to this issue, the majority of courts interpret § 3730(b)(5) to bar a later allegation which "states all the essential facts of a previously-filed claim," even if the later claim "incorporates somewhat different

details." LaCorte, 149 F.3d at 232; see also Lujan, 243 F.3d at 1189; Walburn, 431 F.3d at 971; United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 217-18 (D.C. Cir. 2003). The "common principle is that section 3730(b)(5) precludes a subsequent relator's claim that alleges the defendant engaged in the same type of wrongdoing as that claimed in a prior action even if the allegations cover a different time period or location within a company." Lujan, 243 F.3d at 1188 (internal quotation marks and citation omitted); see also LaCorte, 149 F.3d at 232.

Here, the court must determine which of the complaints – the Duxbury Complaint or the Blair Complaint – was the "first" to assert claims for off-label marketing of Procrit. Stated differently, the court must determine whether the Duxbury Complaint sufficiently alleged an off-label marketing scheme such that the Blair Complaint would be barred by the first-to-file rule. Resolution of this issue requires the court to compare the allegations in the Duxbury and Blair Complaints. See LaCorte, 149 F.3d at 234 n.6 (determining whether later complaint alleges the "same material elements" as claims in the earlier complaint requires "simply [] comparing the original and later complaints"); Merena, 205 F.3d at 102 (same).[13]

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[13] Because neither party raised the issue, I do not address whether the status of the Blair action – i.e., whether the action was "pending" at the time Relators filed their amended complaint – is material to the first-to-file bar in this instance.

2. Duxbury Complaint

Relators assert that three paragraphs in the Duxbury Complaint sufficiently alleged an off-label marketing scheme:[14]

> 40. Another method of inflating reimbursement for use of Procrit was through Phase IV Clinical Trials. Phase IV Trials are defined by the FDA as a method of evaluating a drug in a "real world" clinical setting. Ortho Biotech extensively used Phase IV Marketing Trials as a way to accomplish a number of marketing goals:
>
> a) To provide cash payments to a physician, clinic or hospital which lowers the effective net acquisition cost of the drug. This allows the manufacturer to provide a lower "best price" to physicians than what it reports to the Federal Government, resulting in inflated Medicaid payments for the drug.
>
> b) To provide cash payments to a physician, clinic or hospital to influence the physician to use more of the drug in practice.

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[14] These allegations are found under subsection IV.A, "Ortho Commits AWP Fraud to Increase Market Share For Drugs Covered by Medicare Part B," specifically in subsection IV.A.2.d(2), "Phony Drug Studies." (Duxbury Compl. ¶¶ 40-42.)

c) To provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which is inconsistent with its FDA approved indications and administration methods. In 1997, Ortho Biotech launched a massive Phase IV Marketing Trial which paid physicians to dose Procrit at 40,000iu in a once per week dose instead of the FDA approved dosage of 10,000iu three times per week dosage in cancer-chemotherapy patients. The trial was very successful and the once per week dosage is now universally accepted among oncologists. The trial's success also resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week - an increase of 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia.

41. The approved dosage by the FDA is 10,000iu three times a week. By dosing at 40,000 units once a week, Ortho increases the provider's take, but in doing so, intentionally has established a practice whereby Medicare pays more than the approved FDA dosage. The 40,000iu dosage scheme was successful for Ortho and doctors, but Ortho has not received FDA approval for such dosage. Thousands

of patients have been treated with this dosage. In 1997, Medicare was spending close to $1 billion for EPO.

42. Ortho Biotech's Phase IV Trials also provided thousands of dollars worth of free commercially packaged Procrit to the participating physicians, clinics or hospitals which were billed to Medicare. Again, a simple audit of the account's purchases of Procrit around the time of the trial period and comparison to the amount of Procrit billed to Medicare will identify fraudulent billing practices.

(Duxbury Compl. ¶¶ 40-42) (emphases omitted).

3. The Blair Complaint

The Blair Complaint alleged that OBP:

> engaged in a widespread scheme to market and promote to physicians and pharmacists the use of Procrit at dosing levels exceeding what is approved by the FDA. Relator alleges that the activities of Ortho Biotech in marketing Procrit for these non-approved uses were intended to, and did in fact, cause the submission of hundreds of thousands of false claims for reimbursement to the Medicare and Medicaid programs. . . .

(Blair Compl. ¶ 8.) The complaint states that the predominant dosing regimen for Procrit was initially 10,000 units administered three times weekly, for a total of 30,000 units per week. OBP received approval to manufacture a 40,000 unit vial in 1998 or 1999 in order to accommodate an FDA-approved

dosing regimen for an elective surgery indication. The 40,000 unit vials are dosed once per week. In 2000, OBP unsuccessfully sought FDA approval for a 40,000 unit once per week dosing regimen for the drug's oncology indication. (Id. ¶¶ 18-20.) According to Blair, OBP nonetheless embarked on a scheme to market the 40,000 unit vial to physicians for use with oncology patients, because it desired (1) to increase the revenue stream that would result from selling an extra 10,000 units per week; (2) to increase the use of the drug by physicians due to its convenient once per week, instead of thrice per week, dosage; and (3) to compete with another drug expected to obtain FDA approval in the near future which would only require once per week dosage. (Id. ¶¶ 22-26.)

Blair alleged that OBP carried out its scheme through a variety of marketing and incentive programs, including: (1) direct off-label marketing to medical professionals; (2) influencing the results of purportedly independent clinical studies; (3) illegal payments to medical professionals in the form of "educational grants" and "clerkships;" (4) payments to medical professionals for giving presentations on increased dosage of Procrit; or (5) attending consulting conferences sponsored by OBP which pushed increased dosage of Procrit; and (6) rebate programs offered to induce increased prescriptions of Procrit. (Id. ¶ 27.) The complaint describes each of these alleged methods in further detail in over fifty paragraphs. (See id. ¶¶ 28-79.) Blair alleges that the scheme began in 1998. (Id. ¶ 90.)

The complaint refers to a Phase IV trial known as the "Gabrilove study." (Id. ¶¶ 38-43.) It is unclear whether this is the same Phase IV trial referenced in

the Duxbury Complaint. The Gabrilove study concluded that, for the oncology indication, once weekly dosing at 40,000 units was as effective as three times weekly dosing at 10,000 units per dose. Blair alleged that the study was improperly influenced by OBP's selection of participating physicians and patients. Blair further alleged that OBP used the study to financially reward physicians for proscribing Procrit at higher doses.

Blair's FCA claim was based upon health providers' improper claims for Medicare and Medicaid reimbursement of the 40,000 unit prescription, which was not eligible for reimbursement. "But for Ortho's promotion of off-label uses, most of the ineligible claims for payment of Procrit prescriptions would never have been filed. Every off-label Procrit prescription caused by Ortho Biotech's off-label promotion of Procrit is a false claim caused by Ortho Biotech for the purposes of the [FCA]." (Blair Complaint ¶ 83; see also id. ¶ 88.)

4. Discussion

A superficial comparison of the allegations in the two complaints suggests they are similar. Both allege that oncology providers are improperly dosing Procrit at 40,000iu once per week instead of the FDA-approved dosage of 10,000iu three times a week, resulting in higher reimbursement payments by Medicare and Medicaid. However, similar allegations about the behavior of providers are unimportant; it is OBP's behavior which is relevant in this instance. Providers may lawfully prescribe a

drug for an off-label use; the sine qua non of manufacturer liability is the promotion of the unapproved use.[15] Viewed through this lens, the differences between the Duxbury and Blair Complaints become apparent.

Although the Duxbury Complaint alleged that OBP paid physicians to participate in clinical trials and used Phase IV trials "[t]o provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which is inconsistent with its FDA approved indications and administration methods," (Duxbury Compl. ¶ 40(c)), this allegation does not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit. To the contrary, the complaint alleges that one trial in 1997, and not any other OBP activities or initiatives, led physicians to switch to the higher dosage of Procrit. This bare bones allegation cannot act as a placeholder for the widespread off-label marketing scheme that Relators now wish to allege.[16]

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[15] See Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the House Oversight and Government Reform Committee, 110th Cong. 6-7 (Feb. 9, 2007) (statement of Lewis Morris, Chief Counsel, Office of Inspector General, Department of Health and Human Services) ("While physicians may lawfully prescribe a drug for an off-label use, manufacturers are prohibited from promoting a drug for uses other than FDA-approved uses.").

[16] The Amended Complaint alleges an "inflated dosing scheme" which consisted of (1) promoting off-label dosing of Procrit; (2) promoting the higher-dose of Procrit for an oncology indication even though it was only approved for a surgery (continued...)

See Lujan, 243 F.3d at 1187.[17] The first-to-file rule accordingly would not operate to bar the Blair Complaint's allegations of an off-label marketing scheme. However, as the "first" complaint to allege claims based upon OBP's alleged off-label marketing of Procrit, the Blair Complaint bars Relators' off-label marketing claims. See Grynberg v. Kock Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004). Count III is therefore dismissed.

IV. Rule 9(b)

Defendant next challenges Relators' claims as deficient under Rule 9(b), which requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R Civ. P. 9(b). Rule 9(b) applies to FCA claims and "requires relators to 'provide details that identify particular false claims for

---

indication; (3) paying kickbacks to induce use of Procrit; (4) using "sham drug trials" to falsify eligibility for Medicare reimbursement of a higher dose of Procrit; and (5) changing the vial size in which free Procrit was distributed. (Am. Compl. ¶ 132.)

[17] Indeed, correspondence between the plaintiff and the government suggests that the Duxbury Complaint failed to put the government on notice of OBP's alleged off-label marketing scheme. (See June 18, 2004 Letter (Docket # 78), 6 ("We believe the following paragraph describes a more important and damaging fraud identified in Mr. Duxbury's complaint, which we described (see Complaint ¶¶ 40-42) but are not sure you have grasped based on your letter and the interview of Mr. Duxbury.").)

payment that were submitted to the government.'" Rost, 507 F.3d at 731 (quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004)). Because the court only has jurisdiction over Duxbury's allegations of kickbacks occurring from 1992 to 1998 (see supra Section III.A.3.a), I will only evaluate those claims for sufficiency under Rule 9(b).

FCA liability attaches only to false claims, not to any underlying fraudulent activity or to the government's wrongful payment. "Evidence of an actual false claim is the sine qua non of a False Claims Act violation." Karvelas, 360 F.3d at 225 (internal quotation marks and citation omitted). The Amended Complaint alleges particularized details about OBP's underlying scheme to induce doctors to prescribe Procrit by granting them a variety of kickbacks, including rebates and other off-invoice discounts, educational grants, and the like. (See, e.g., Am. Compl. ¶ 211 (identifying particular amounts of money or percentages of discounts given to particular providers).) However, it is not enough to allege details of the scheme if there are not also particularized allegations regarding the false claims that were actually submitted to the federal government. As the First Circuit stated in Karvelas, a case in which a relator alleged that a health care provider submitted false Medicare and Medicaid claims to the federal government,

> Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b). However, such pleadings

> invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action. As applied to the FCA, Rule 9(b)'s requirement that averments of fraud be stated with particularity . . . means that a relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in the complaint. However, . . . we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Id. at 232-33 (footnotes and internal quotation marks and citation omitted).

Karvelas suggests that Rule 9(b) may be satisfied if the complaint as a whole is sufficiently particular to pass muster under the FCA, although some questions remain unanswered. Karvelas, 360 F.3d at

233 n.17. Nonetheless, even giving Duxbury the "benefit of such flexibility," Rost, 507 F.3d at 732, the allegations are inadequate because they are indistinguishable from those found insufficient in Karvelas. In Karvelas, the relator, a former employee of the defendant health care provider, filed a 93-page complaint which alleged sixteen complex schemes of fraud "at considerable length." Karvelas, 360 F.3d at 232-33. However, the complaint "never specifie[d] the dates or content of any particular false or fraudulent claim allegedly submitted for reimbursement by Medicare or Medicaid," and "did not set forth the specifics . . . of any one single cost report, or bill, or piece of paper that was sent to the Government to obtain funding." Id. at 233. Although the relator alleged serious violations of federal regulations, his allegations were insufficient to support a claim under the FCA because he "fail[ed] to identify with particularity any actual false claims that the defendants submitted to the government." Id. at 235.

The same is true here. Although Duxbury identifies providers and approximate amounts of free samples, discounts, "off-invoice" rebates, or educational grants, he fails to identify a single false claim consequently filed by these providers. (See, e.g., Am. Compl. ¶ 211.) In the closest case, Duxbury alleges that St. Joseph's Hospital in Tacoma, Washington, was given "off-invoice" rebates of 14% for the purchase of Procrit, and submitted "approximately 4,800 claims a month for Medicare reimbursement." (Id. ¶ 211(a).) However, this allegation fails to provide even one (much less "some") of the specifics required by Karvelas for "at least some of the claims," viz., the "dates of the

claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices . . . ." 360 F.3d at 232-33.

Duxbury argues that he cannot identify all the false claims submitted to the government because the claims "were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control." (Am. Compl. ¶ 232.) Yet, this is precisely the point of requiring relators to identify particular claims, for under Karvelas and Rost the court is not permitted to surmise that false claims "must have" occurred as a result of defendant's conduct. "No matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendants' activities." Rost, 446 F. Supp. 2d at 28 (citing Karvelas, 360 F.3d at 235).

Similarly, although Duxbury alleges that providers submitted HCFA Forms 1500 and 2552 and other certifications of compliance with the anti-kickback statute in order to get false claims paid (see Am. Compl. ¶¶ 230, 234-37), the mere identification of the template forms which providers used to submit reimbursement in the abstract is insufficient when not tied to a particular claim filed by a particular provider. Karvelas, 360 F.3d at 231 n.13 (Rule 9(b) standard applies to documents that are "regularly-

filed," i.e., relator is not absolved of the requirement to plead particulars simply because the document is one routinely filed with the government).[18]

V. Conclusion

Although the court has subject matter jurisdiction to hear Duxbury's claims of alleged kickbacks which occurred during his employment at OBP, his allegations lack the particularity required under Rule 9(b) and this Circuit's precedent. This complaint was initially filed in 2003 and unsealed in 2005, and it is now 2008. Relators have already amended their complaint once as of right, and the court is not inclined to allow further amendments.

---

[18] Duxbury alleges that the kickbacks violated 31 U.S.C. §§ 3729(a)(1) and (2). Section 3729(a)(1) imposes liability upon a person who "knowingly presents, or causes to be presented . . . a false or fraudulent claim for payment or approval" to the United States Government. Section 3729(a)(2) imposes liability upon a person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." Neither party suggests that the particularity requirements should be analyzed separately for the two subsections, and the court does not deem it necessary, as its analysis applies equally to both subsections. See Rost, 507 F.3d at 733 (rejecting assertion that subsections must be analyzed separately). Duxbury also includes a puzzling reference to stating a claim under § 3732(b), which provides federal court jurisdiction for state law claims based upon FCA violations. (See Am. Compl. Count I, at 58.) As the complaint does not allege violations of any specific state law (in Duxbury's sales region in the western United States or otherwise), § 3732(b) is inapplicable.

Accordingly, defendant's motion to dismiss the amended complaint with prejudice (Docket # 56) is ALLOWED.[19]

Judgment may be entered for defendant.

January 28, 2008
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES
DISTRICT JUDGE

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[19] As the government has not intervened, the court does not dismiss this action with prejudice as to the United States. See United States ex rel. Williams v. Bell Helicopter Textron Inc., 417 F.3d 450, 455 (5th Cir. 2005) (improper to dismiss FCA claims with prejudice as to United States when government did not intervene in qui tam action which was deficient under Rule 9(b)).

APPENDIX C

United States Court of Appeals
For the First Circuit

No. 08-1409

UNITED STATES, ex rel. Mark Eugene Duxbury and Dean McClellan

Plaintiff

MARK EUGENE DUXBURY; DEAN MCCLELLAN

Plaintiffs - Appellants

v.

ORTHO BIOTECH PRODUCTS, LP

Defendant - Appellee

Before

Lynch*, Chief Judge,
Torruella, Siler**, Boudin*,
Lipez and Howard, Circuit Judges.

ORDER OF COURT

Entered: September 4, 2009

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* Chief Judge Lynch and Judge Boudin are recused and did not participate in the consideration of this matter

** of the Sixth Circuit, sitting by designation

Pursuant to First Circuit Internal Operating Procedure X(C), the petition for rehearing en banc has also been treated as a petition for rehearing before the original panel. The petition for rehearing having been denied by the panel of judges who decided the case and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and petition for rehearing en banc be denied.

By the Court:

/s/Richard Cushing Donovan, Clerk

cc:
Jan Richard Schlichtmann
Kathleen C. Chavez
Robert M. Foote
Paul E. Simmerly
Sara M. Bloom
Patricia M. Connolly
Douglas N. Letter
Charles W. Scarborough
Jaime Ann Yavelberg
Susan L. Burke
Geoffrey E. Hobart
Ethan M. Posner
Rebecca Rohr
Clevland Lawrence, III

APPENDIX D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.* MARK EUGENE DUXBURY and DEAN McCLELLAN Relators, v. ORTHO BIOTECH PRODUCTS, L.P., Defendant.	CIVIL ACTION: 03-CV-12189-RWZ **(LEAVE TO FILE AMENDED COMPLAINT GRANTED 10-24-06)**

FIRST AMENDED COMPLAINT

AND

DEMAND FOR JURY TRIAL

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VI. FACTUAL BACKGROUND

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C. Defendant's Illegal Conduct.

C(1). Defendant's Scheme to Increase the Spread Between AWP and the Effective Cost of Procrit

. . . .

b. Defendant's Kickbacks to Increase the Spread Between AWP and the Effective Cost of Procrit

(1) Free Drug

91. Defendant, through Relators and other sales personnel and marketing representatives, also provided free commercially packaged and labeled drugs to Providers as a means of lowering actual acquisition cost of Procrit to Providers. The free drugs were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread" between actual acquisition cost and Medicare reimbursement rates based on AWP.

92. Defendant specifically told Providers to bill patients for the free Procrit, which Defendant knew was unlawful.

93. Both Relators have personal knowledge that Defendant commonly directed its sales representatives to provide free Procrit to Providers

and instruct the Providers to submit claims for Medicare reimbursement for said Procrit.

94. Free product is not used by Defendant in calculating or reporting the AWP despite the fact that the substantial quantities of free drug given to Providers effectively lowered net acquisition cost. The failure to include free drugs in calculating the AWP, contributed to the inflated AWP.

95. Although Defendant provided free product and marketed free Procrit as a way to lower the Providers' actual cost of Procrit. Defendant did not include the value of the free product in calculating the AWP for Procrit. Thus, Defendant effectively and improperly passed on the cost of the free product directly to Medicare.

96. The free Procrit provided to Providers by Defendant's sales representatives, including but not limited to Relators, were drug samples within the meaning of 21 U.S.C. § 353(c)(1). Defendant provided the free Procrit with the illegal intent that Provider's submit claims for reimbursement to Medicare for said free drug.

97. Defendant offered substantial quantities of free Procrit through "Patient Trial Cards." These are sequentially numbered documents that identify the Provider who received the drug and the representative who provided the drug. There were thousands of "Patient Trial Cards" provided to sales representatives, each of which was worth well over one thousand dollars ($1,000) in free Procrit. For example, Relator McClellan had over 400 Patient Trial Cards in his possession at one time. Medicare was billed for free Procrit and the free Procrit was not accounted or in calculating AWPs. Relator

McClellan has copies of hundreds of "Patient Trial Cards" that he gave directly to Providers with the intent that the Providers would submit claims for reimbursement to Medicare for the free Procrit.

98. Relators have direct and independent knowledge that Defendant gave free samples of Procrit to Providers to induce them to use Procrit and lower the actual cost of the drug.

99. Both Relators, at the direction of and as agents of Defendant, personally and directly gave free Procrit to Providers and told providers to submit claims for reimbursement to Medicare for the free Procrit.

100. Defendant routinely referred to free Procrit as "cash." Defendant employees Thomas Amick, William Pearson, Robert Ashe, George Mooney, William Ball, John Woodhouse, Keith Wood, Michael Barton and Robert Nelson instructed Relator Duxbury to treat free Procrit as a "cash" equivalent incentive to Providers.

101. Defendant employees which include numerous managers during this time period, including but not limited to Dwayne Marlowe, James Scelfo, Robert Ashe instructed Relator McClellan to treat free Procrit as a "cash" equivalent incentive to Providers.

102. For example, in or about February 2001, one of Defendant's product specialists reported to Defendant's regional manager, Dwayne Marlowe, in a Status Report that an oncology clinic within his territory had failed to obtain reimbursement for approximately $8,500 worth of Procrit. Marlowe instructed the product specialist to provide free Procrit to the account equal in value to the clinic's

reimbursement losses. Marlowe instructed the product specialist to submit to Defendant Patient Trial Cards on the clinic's behalf, to get it free Procrit. The product specialist would have a doctor sign numerous cards at a time so as not to draw attention, and then every two weeks he would submit just a few of them to Defendant for fulfillment. These allegations are supported by contemporaneously generated documents in the possession of Relator McClellan.

103. Both Relators have direct and independent knowledge of Defendant's unlawful practices, promotional and marketing policies, and illegal schemes related to the provision of free Procrit to Providers with the direction to Providers to submit claims for reimbursement to Medicare.

(2) Discounts and Rebates

104. Defendant offers Providers discounts and rebates for Procrit purchases to induce them to buy Procrit.

105. Both Relators have direct and independent knowledge that Ortho provided discounts, rebates, and other financial inducements to stimulate the sale of Procrit and lower the actual cost of purchasing Procrit.

106. Both Relators possess documents showing that as a sales representative of Defendant they provided discounts, rebates, and educational grants directly to Providers purchasing Procrit.

107. Both Relators, at the direction of and in agency for Defendant, gave Providers "off-invoice" hidden discounts, grants, rebates and other

incentives to lower the actual acquisition cost of Procrit.

108. Relator Duxbury also possesses documentation of rebates given in 1993 by Defendant to the Mid-Columbia Kidney Center, for purchases of Procrit. Again, Relator Duxbury has independent and direct knowledge of the provision of the rebate to Mid-Columbia Kidney Center, because Defendant directed Relator Duxbury to provide the off-invoice rebate. Defendant represented to Relator Duxbury that the rebate was provided "off-invoice" for the exclusive purpose of inducing more Procrit purchases by lowering the actual acquisition cost and increasing the kidney center's profit to be made by the AWP spread at the expense of Medicare.

109. Both Relators possesses first hand direct and independent knowledge that Defendant's purpose of giving cash payments to physicians to serve on Advisory Boards was to influence them to prescribe and advocate the prescription of Procrit. Both Relators were told by Defendant that the purpose was to influence the providers to prescribe Procrit. Both Relators were also given a February 26, 1997 memorandum, to Hematopoietic Product Specialists, from Defendant's manager William Pearson re: Advisory Board Member Interaction, that set forth in writing the unlawful intent to provide cash payments as an inducement to physicians to prescribe Procrit.

110. As of August 13, 2003, Defendant guaranteed physicians a discount of 6% (and potentially up to 10%) off the list price if they purchased Procrit.

111. In an April 13, 2004 internal training presentation, Defendant's Executive Director of Contracting and Government Contracts Tom Hiriak described Defendant's discount and rebate program for physicians. He explained that physicians can purchase Procrit off several discount programs" that "provide a 5% off-invoice (upfront) discount." However, this discount is not provided directly by Defendant. Rather, through a "chargeback" process the drug distributor provides the discount and "'charges back' to collect the 5% discount."

112. Rebates of 5% were normal until approximately 2002, when Amgen released Aranesp. Until then, Procrit was 17% cheaper than Amgen's competing product, Epogen.

113. Since the introduction of Aranesp, Defendant has marketed an aggressive rebate program.

114. A copy of a 2003 promotion piece for physicians refers to rebates "paid in product."

115. The Hiriak internal training presentation states that Ortho Biotech rolled out two physician rebate programs in January 2004. As of that date, physicians could qualify for rebates of between 15.5% and 20% off the discounted price, depending on their purchase volume.

116. Several additional rebate percentage points were authorized in March 2004.

117. Hospitals receive reimbursement under an "APC" code. As of early 2004, they received 73.4 percent of AWP. Because the reimbursement is based in part on AWP, Defendant did "market the

spread" between the actual sales price to hospitals and AWP.

118. In 2003, Defendant had a rebate program offering hospitals an 8% rebate.

119. Defendant's executives trained sales representatives on calculating the Medicare reimbursement for Procrit at annual sales meetings. Combined with the promotional materials described above, sales representatives were equipped to calculate the spread between a customer's net cost and the Medicare reimbursement.

(3) Unrestricted Educational Grants

120. Defendant maintained large pools of money to be disbursed as unrestricted educational grants in what was called "business development grants" later renamed the S.A.F.E. program. Each unrestricted educational grant required a written request from the sales representative to his/her manager and included a description of what benefit to Defendant is expected in return for the grant. Defendant used these grants as "kickbacks" to buy influence with physicians and hospitals. These "kickbacks" were directly tied to the Providers' purchase of Procrit.

121. One example of this type of "kickback" given to Providers to purchase Procrit is Relator Duxbury possesses documentation of a ten thousand dollar ($10,000) and twenty thousand dollar ($20,000) unrestricted grants that Defendant gave St. Joseph's Hospital in Tacoma, Washington in 1992 and 1993 conditioned upon the purchase of Procrit. The grants were given in connection with and in consideration for continued purchase of Procrit, and

was used as a way to lower the actual acquisition cost of Procrit to the Provider.

122. In order to convert a hospital with a large dialysis center to Procrit, Defendant provided unrestricted educational grants totaling $30,000 during an 18-month period beginning in the spring of 1993. The account was St. Joseph's Hospital in Tacoma, Washington. The grants substantially reduced the effective net acquisition price (which was already 15% below AWP) for Procrit and were not used by Defendant in reporting its AWP.

123. In 2002, a site of U.S. Oncology, a nationwide oncology practice, within the district of Defendant's manager James Scelfo, was given an annual grant of $50,000 to support a "Life Beyond Cancer" educational program. In 2003, however, after Defendant lost U.S. Oncology's contract to provide it with Procrit, Defendant reduced its funding to $10,000.

(4) Membership on Advisory Boards

124. Pharmaceutical companies established Advisory Boards to allow the drug manufacturer to bring medical experts to a central location where they can hear presentations on the manufacturer's products, new research areas and information regarding off-label use. The Advisory Board members are expected to provide feedback to the manufacturer on the quality of the information they heard, evaluate the relative importance of clinical data they were presented, and reinforce existing research directions or suggest new ones.

125. Defendant used Advisory Boards not to gather new research ideas, but to give cash and benefits to oncologists to promote sales of its drug.

126. In a memorandum to Defendant's Procrit sales force dated February 26, 1997, National Field Sales Manager Bill Pearson explained the purpose of Ortho Biotech's Advisory Boards: "One of the operating strategies for our Integrated Business Plan is to ***develop thought leader endorsement to establish PROCRIT as standard of care***. Our Clinical Affairs Department has been very active in developing tumor specific, HIV, and fatigue advisory boards to develop thought leader endorsement and establish PROCRIT as the standard of care in treating anemic cancer patients."

127. Defendant used Advisory Boards to make cash payments to influential physicians and take them to meetings at resorts in order to gain influence among leaders in the oncology community. At these meetings, minimal time was spent discussing information of medical value.

(5) Phony Drug Studies

128. Another method of inflating reimbursement for use of Procrit was through phony drug studies. Phase IV clinical trials are defined by the FDA as a method of evaluating a drug in a "real world" clinical setting. Defendant extensively used a Phase IV marketing trial as a way to accomplish a number of marketing goals:

a) To provide cash payments to a physician, clinic or hospital which lowered the effective net acquisition cost of the drug. This allowed the manufacturer to provide a

lower "best price" to physicians than what it reported to Federal or State Governments, resulting in inflated Medicare and Medicaid payments for the drug;

b) To provide cash payments to a physician, clinic or hospital to influence the physician to use more of the drug in practice.

c) To provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which was higher than the FDA-approved dosage. In 1997, Defendant launched a massive Phase IV marketing trial to increase the dosage – and Government reimbursement – by 33% for each Medicare Beneficiary receiving Procrit for Other Hidden and Improper Inducements and Price Reductions

(6) Other Hidden and Improper Inducements and Price Reductions

129. Defendant has provided and/or arranged for many other non-public financial inducements to stimulate sales of Procrit at the expense of Medicare and Medicaid. Such inducements included volume discounts, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers' net cost of purchasing Procrit. And again, the value of these services was kept "off the book," so as to not be reflected in the AWP, which in turn inflated the AWP.

130. During the time of both Relators' employment, Defendant offered substantial discounts, rebates, unrestricted educational grants, and free commercially packaged Procrit to Providers in order to create a lower effective net purchase price and a greater profit spread from the inflated AWP reported to Medispan, *Red Book*, and other publishers. Defendant used surrogate companies like Charise Charles, Lt. and MarketCheck, Inc., to facilitate these schemes. The surrogate companies would use the U.S. mail to send rebates to Providers throughout the country. These rebates were hidden from Medicare and were not accounted for in calculating Defendant's reported AWP for Procrit.

. . . .

D. Defendant's Illegal Conduct Caused False Claims to be Submitted to Medicare

D(1). RELATOR DUXBURY'S ACCOUNTS:

211. From 1992 through 1998, Relator Duxbury sold over 13 million dollars worth of Procrit on behalf of the defendant. Relator Duxbury has specific knowledge that approximately 80 percent of the Procrit sales that he generated were submitted by his accounts as false or fraudulent claims for Medicare reimbursement. This knowledge is based on his personal knowledge, observation and direct communications with the accounts he developed and maintained during his employment and is supported by the documents contemporaneously generated by Relator Duxbury and defendant during the term of his employment.

The following accounts submitted false and fraudulent claims for Medicare reimbursement:

a. St. Joseph's Hospital in Tacoma, Washington purchased approximately 1.7 million to 2 million dollars a year of Procrit from Defendant during the period between approximately 1993 through 1997, which was submitted to and reimbursed by Medicare. The Procrit was administered for the treatment of patients with dialysis related anemia. During this period St. Joseph's submitted approximately 4,800 claims a month for Medicare reimbursement. St. Joseph's was provided so-called "unrestricted educational grants" by the Defendant totaling more than $30,000, which Defendant intended to be and was in fact not a "grant" but a "kickback" for St. Joseph's purchase of Procrit. These "kickbacks" were paid out of Defendant's "Regional Business Development" pool which was a "slush fund" to induce the purchase of Procrit by accounts. Defendant intentionally failed to report these payments to the US Government in order to keep secret the profit spread between the rate upon which Medicare reimbursed medical providers like St. Joseph's for Procrit. St. Joseph's contract with Defendant provided St. Joseph's with an "off-invoice" rebate of 14% for the purchase of Procrit. Defendant intentionally failed to report these "off-invoice" rebates to the US Government in order to keep the Medicare reimbursement rate to Providers like St. Joseph's at artificially inflated levels so that the Providers could benefit from the profit-spread between the Provider's actual acquisition cost and the Medicare reimbursement rate. Defendant actively marketed Procrit to St. Joseph's by representing to St. Joseph's that it could profit on the

administering of Procrit by exploiting the profit spread so that St. Joseph's could "turn the dialysis unit into a profit center". As a result of Defendant's actions, Defendant knowingly caused the presentation by St. Joseph's of these false and fraudulent claims to the United States Government.

b. In 1998 Rainier Oncology of Puyallup, Washington was provided more than $20,000 of free commercially packaged Procrit from Defendant under the direction of John Woodhouse (Seattle District Manager) under the guise of running an unlawful mini-trial so that Rainier Oncology could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Rainer Oncology in order to induce the provider to administer Procrit at the "off-label" dosage of 40,000 IU 1X/week. As a result, Defendant knowingly caused the presentation by Rainier Oncology of these false claims to the United States Government.

c. In 1993 Memorial Clinic in Olympia, Washington was provided approximately $15,000 of free commercially packaged Procrit from Defendant under the direction of Robert Nelson (Seattle District Manager) so that Memorial Clinic could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Memorial Clinic in order to induce the provider to purchase Procrit. Memorial Clinic was reimbursed by Medicare for the free commercially packaged Procrit. In 1993-98

Defendant induced Memorial Clinic to use the fraudulently obtained Medicare reimbursement to purchase additional Procrit by giving Memorial Clinic "off-invoice" rebates of 5-8% so that Memorial Clinic would receive Medicare reimbursement which was significantly more than what they actually paid for the product. As a result, Defendant knowingly caused the presentation by Memorial Clinic of these false claims to The United States Government.

d. In 1997-98 Western Washington Cancer Treatment Center in Olympia, Washington received more than $5,000 of free commercially packaged Procrit from Defendant under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase Procrit and to administer Procrit at the "off-label" once a week dosing regimen. Western Washington was reimbursed by Medicare for the free commercially packaged Procrit. As a result, Defendant knowingly caused the presentation by Western Washington of these false claims to The United States Government.

e. In 1993, the Mid Columbia Kidney Center in Kennewick, Washington under the direction of Dr. John Boykin, submitted claims to Medicare and was subsequently reimbursed by Medicare approximately $75,000 for the administering of Procrit to Mid Columbia Kidney Center's patients. Mid Columbia Kidney Center's agreement with Defendant provided Mid Columbia Kidney Center with an "off-invoice"

rebate of 5-8% for the purchase of Procrit. Defendant intentionally failed to report these "off-invoice" rebates in order to keep secret the "profit spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to Mid Columbia Kidney Center by representing that Mid Columbia Kidney Center could profit on the administering of Procrit by exploiting the "profit-spread" between the actual acquisition cost and the Medicare reimbursement rate. As a result of Defendant's actions, Defendant knowingly caused the presentation by Mid Columbia Kidney Center of these false and fraudulent claims to The United States Government.

f. In 1994-1996, St. Peter's Hospital in Olympia, WA, submitted claims to Medicare and was subsequently reimbursed by Medicare for approximately two million dollars of Procrit. St. Peter's contract with Defendant provided St. Peter's with an "off-invoice" rebate of 14% for the purchase of Procrit. Defendant intentionally failed to report to the US Government these "off-invoice" rebates in order to keep secret the "profit spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to St. Peter's by representing to St. Peter's that it could profit on the administering of Procrit by exploiting the "profit-spread". As a result of Defendant's actions, Defendant knowingly caused the presentation by St. Peter of these false and fraudulent claims to The United States Government.

g. In 1994-1997 Memorial Clinic Oncology Group in Washington purchased about approximately

$750,000 of Procrit. Memorial Clinic Oncology Group's agreement with Defendant provided Memorial Clinic Oncology Group with an "off-invoice" rebate of 5% for the purchase of Procrit. Defendant intentionally failed to report to the US Government the "off-invoice" rebates in order to keep the "profit spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to Memorial Clinic Oncology Group by representing to Memorial Clinic Oncology Group that it could profit on the administering of Procrit by exploiting the "profit-spread". In 1998 Memorial Clinic's Oncology Department participated in a sham "Phase IV" trial through which they received more than $32,000 of free drug that was intended to be submitted for Medicare reimbursement as if the Provider had paid for the drug. Approximately sixty percent of Procrit administered by Memorial Clinic Oncology Group was submitted and reimbursed by Medicare. As a result of Defendant's actions, Defendant knowingly caused the presentation of Memorial Clinic Oncology Group's false and fraudulent claims to the United States Government. Memorial Clinic Oncology Group also received approximately $50,000 in free commercially packaged Procrit from the Defendant, so that Memorial Clinic Oncology Group could submit the free Procrit to and be reimbursed by Medicare. Memorial Clinic Oncology Group was reimbursed by Medicare for the free commercially packaged Procrit. As a result, Defendant knowingly caused the presentation by Memorial Clinic Oncology Group of these false and fraudulent claims to The United States Government.

h. In 1996 Swedish Hospital in Seattle, Washington under the direction of Defendant's Regional Business Director, George Mooney and Manager Hilton Dempsey was given cash in the form of a so-called "unrestricted educational grant" in the amount of approximately $15,000. In actuality the payment was a monetary inducement or "kickback" to induce the provider to purchase Procrit. Provider subsequently purchased over $100,000 of Procrit of which approximately 50% was submitted for Medicare reimbursement. Defendant intentionally failed to report to the US Government the cash payment made to Swedish Hospital in order secret the "profit-spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate. As a result, Defendant knowingly caused the presentation by Swedish Hospital of these false and fraudulent claims to The United States Government.

. . . .

VIII. COUNTS

COUNT I

KICKBACKS IN VIOLATION OF THE FALSE CLAIMS ACT
(31 U.S.C. §§ 3729(a)(1), (a)(2), and 3732(b))

226. Relators reallege and incorporate by reference the preceding allegations.

227. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.

228. Defendant gave kickbacks to providers and hospitals to induce them to prescribe Procrit. These kickbacks included free Procrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria.

229. Defendant's kickbacks caused providers and hospitals to submit false claims for payment to Medicare for Procrit. In addition, by giving off-invoice discounts to Providers and hospitals that resulted in actual invoices to be false, Defendant used a false record or statement to get a false claim paid by the Government.

230. Defendant caused Providers to submit/use the HCFA Form 1500, and other such forms as a false statement/record to get a false claim paid.

231. Defendant published a false AWP in the pharmaceutical compendia, thus using a false record/statement to get a false claim paid by the government.

232. Relator cannot identify at this time all of the false claims caused by Defendant. The false claims were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control. Specification of the vast number of false claims would be burdensome to the Court and the parties. The time period of the false claims was from December 1992 to the present. Such claims were made across the United States.

233. In submitting these claims for payment, providers and hospitals expressly or impliedly certified that they complied with the anti-kickback statute.

234. This certification included the Certification Statement in the Medicare Health Care Provider/Supplier Application, OMB Approval No. 0938-0685. This Certification Statement reads in part: "I understand that payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions (including the anti-kickback statute and the Stark law) . . . ."

235. In addition, hospital cost reports (Form HCFA-2552) provide:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified by this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines, and/or imprisonment may result.

236. The form also requires the following certification by an officer or administrator of the health care provider:

> I hereby certify that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by . . . (Provider Name(s) and Number(s)) for the cost reporting period beginning . . . and ending . . . and that to the

> best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.

237. In addition, on hospitals' cost reports, they certify that the reports are "true, correct, and complete" and "prepared . . . in accordance with applicable instructions, except as noted."

238. Because Defendant had provided the providers and hospitals kickbacks to induce them to use Procrit, all these certifications were false.

239. Defendant's kickbacks were a substantial factor causing the submission of the false claims for payment for Procrit. Defendant used kickbacks to induce providers and hospitals to use Procrit to treat dialysis patients and to submit reimbursement claims for such prescriptions. In the absence of these kickbacks, the providers and hospitals would not have purchased Procrit. In addition, Defendant used kickbacks to convince providers and hospitals to prescribe 40,000 units of Procrit 1X/per week to oncology patients and to submit corresponding reimbursement claims, and in the absence of the kickbacks providers and hospitals would have prescribed 30,000 units in 10,000 IU 3X/week of Procrit or the Providers would have used another alternative product or therapy.

240. Providers' and hospitals' submission of false claims for payment to Medicare, were a foreseeable result of Defendant's kickbacks. Further, not only were they foreseeable but they were the intended consequence of the kickbacks.

241. Defendant's kickbacks would have been material to the Government's decision to pay the reimbursement claims for Procrit. Compliance with the anti-kickback statute is central to the reimbursement plan of Medicare. If the Government had known that the reimbursement claims were induced by Defendant's kickbacks, it would not have paid them.

242. Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the United States government false and fraudulent claims, records, and statements in order to obtain reimbursement for health care services provided under Medicare.

243. Providers' false and fraudulent claims were submitted for reimbursement based on AWP to Medicare on a HCFA 1500.

244. These claims for payment were false because (i) they were not for a use eligible for reimbursement under the Medicare Act, (ii) they did not disclose the illegal scheme that induced the claims for reimbursement at inflated doses, (iii) were seeking reimbursement based on a false and inflated AWP; (iv) were for reimbursement of Procrit that Defendant gave to at no cost, and/or (iv) they were induced by illegal kickbacks and other monetary incentives.

245. Through the acts described above and otherwise, Defendant and its agents and employees

knowingly made, used, and/or caused to be made or used false records and statements in order to get such false and fraudulent claims paid and approved by the United States government.

246. The United States and its fiscal intermediaries/carriers, unaware of the falsity of the records, statements, and claims made or submitted by Defendant and its agents and employees paid and continue to pay Defendant for claims that would not be paid if the truth were known.

247. By reason of the Defendant's false records, statements, claims, and omissions, the United States has been damaged in the amount of many millions of dollars in Medicare reimbursement costs.

. . . .

IX. PRAYER FOR RELIEF

WHEREFORE, Relators pray for judgment against Defendant as follows:

A. That Defendant ceases and desists from violating 31 U.S.C. § 3729 *et seq.*;

B. That the Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained as a result of Defendant's actions, as well as a civil penalty against Defendant of $11,000 for each violation of 31 U.S.C. § 3729;

C. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

D. That Relators be awarded all costs and expenses of this action, including attorneys' fees; and

E. That the United States and Relators receive all such other relief as the Court deems just and proper.

X. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury.

Dated: October 14, 2006

Respectfully submitted by his attorneys,

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(4)

No. 09-654

Supreme Court, U.S.
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In The
Supreme Court of the United States

ORTHO BIOTECH PRODUCTS, L.P.,

Petitioner,

v.

UNITED STATES EX REL. CHINYELU DUXBURY,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

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QUESTIONS PRESENTED

Whether certiorari should be denied in this case under the False Claims Act, 31 U.S.C. §§3729-3733, alleging a nationwide Medicare fraud scheme:

A. Where the First Circuit ruling, that "the plain and unambiguous terms" of the "original source" exception, 31 U.S.C. §3730(e)(4)(B), to the "public disclosure bar," 31 U.S.C. §3730(e)(4)(A), require the relator to "provide[ ] the information to the Government *before filing an action*" and "does not impose any other timing requirement" that the information should have been provided "*before* the public disclosure," followed the clear dictates of *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007) and, since *Rockwell*, no Circuit has held to the contrary; and,

B. Consistent with the precedent of the other Circuits, the First Circuit, after a detailed factual analysis, ruled that Relator satisfied the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure regarding allegations of fraud where Relator "alleged the submission of false claims across a large cross-section of providers that alleges the 'who, what, where, and when' of the allegedly false or fraudulent representation" which "supports a strong inference that such claims were also filed nationwide."

RESPONDENT PARTIES TO THE PROCEEDING

The district court in *U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, USDC DMa CA No. 03-12189-RWZ, by order dated December 10, 2009, substituted Relator Mark Eugene Duxbury's surviving spouse, Chinyelu Duxbury, as the Relator.

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INTRODUCTION

Ortho's Petition seeking certiorari of the First Circuit's decision in *U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13 (1st Cir. 2009) should be denied. Ortho erroneously claims that the First Circuit took the wrong side of what Ortho misleadingly suggests is an ongoing conflict among the Circuits as to whether the "original source" exception, 31 U.S.C. §3730(e)(4)(B), to the "public disclosure bar," 31 U.S.C. §3730(e)(4)(A), means what it says when it explicitly requires, in cases where there has been a "public disclosure" of an alleged *qui tam* fraud, that the relator with "direct and independent knowledge" of the fraud provide their information to the government *"before filing an action."* Ortho wrongly argues it is necessary to read into the statute the additional requirement that the relator provide the information to the government *"prior to the public disclosure."* Contrary to Ortho's assertions, the First Circuit's ruling that a relator is required by the plain words of the statute to provide the information underlying its *qui tam* suit to the Government *"before filing an action"* and not, by any form of words, *"prior to any public disclosure,"* is completely consistent with this Court's decision in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007) that "disposition[s]" regarding the requirements of "original source" status "begin with subparagraph B standing on its own" and the statute explicitly requires relators to have "direct and independent knowledge" of the information underlying their complaint because

the statute requires the relator to provide the government the information "*before filing an action*" and that is "the information one would expect a relator to 'provide to the Government *before filing an action.*'" Ortho's assertions notwithstanding, while, prior to *Rockwell*, there may have been confusion by a minority of Circuits that it was appropriate to read into the statute the additional requirement that the information had to be provided to the Government "*prior to the public disclosure*" or shown that the relator "had a hand in the public disclosure," that is not the present situation. Since *Rockwell*, *no* Circuit, has actually based a decision on the proposition that §3730(e)(4)(B) imposes such an additional requirement. See Reasons For Denying The Writ, Section I.

In addition, Ortho misleadingly suggests to the Court that the First Circuit's ruling that Relator's complaint satisfied the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure was based on Relator "*not*" "identify[ing] a particular false or fraudulent claim," Pet. at 33, and therefore the First Circuit's ruling was in conflict with other Circuits requiring "some representative examples of false claims to support allegations of a wide-ranging fraud." Pet. at 26. On the contrary, as the First Circuit makes manifest, its ruling finding the Relator pleaded fraud with sufficient particularity was based on the court's detailed analysis of relator's allegations and the court's finding that: Relator "alleged facts that support[ed] his claim that [defendant] intended to cause the submission of false claims" and

"alleged facts that false claims were in fact filed by the medical providers he identified . . . [that] further support[ed] a strong inference that such claims were also filed nationwide." Pet. 37a. The First Circuit's ruling that Relator's detailed factual allegations that "false claims were in fact filed by the medical providers he identified" and that these particular instances of fraud "further support[ed] a strong inference that such claims were also filed nationwide" is the personification of the "representative example" rule adopted by other Circuits in cases involving a complex fraud scheme of long duration. As has been consistently held by other Circuits, Rule 9(b)'s particularity requirements are fulfilled where the Relator in such cases provides "representative examples of false claims" in order "to support allegations of a wide-ranging fraud." See Reasons For Denying The Writ, Section II.

In light of the First Circuit's following the clear dictates in *Rockwell* that the plain words of the statute govern the requirements for granting "original source" status, the fact that since *Rockwell* was decided there has not been an actual rejection by any of the Circuits of this proposition, and the First Circuit's well considered review of the Relator's detailed allegations of fraud that is completely consistent with the standards established by Rule 9(b) and the other Circuits, there is no demonstrated need for certiorari to be granted.

STATEMENT

This Petition arises out of the First Circuit's affirmance of the lower court's ruling that the plain words of the "original source" exception, 31 U.S.C. §3730(e)(4)(B), to the "public disclosure bar," 31 U.S.C. §3730(e)(4)(A),[1] explicitly require, in cases where there has been a "public disclosure" of an alleged *qui tam* fraud, that the relator with "direct and independent knowledge" of the fraud provide their information to the government *"before filing an action"* and does not also require that the information be provided *"prior to the public disclosure."* It also seeks review of the First Circuit's ruling that in a complex nationwide fraud scheme of long duration

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[1] 31 U.S.C. §3730(e)(4) provides:

[The "Public Disclosure Bar"]

(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

[The "Original Source" Exception]

(B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

involving the alleged submission of numerous false claims, the heightened particularity requirements of Rule 9(b)[2] are satisfied if the plaintiff alleges sufficient facts of the "who, what, where, and when" of the submission of a cross-section of claims or representative examples of such fraud that support "a strong inference that such claims were also filed nationwide."

As detailed in his Complaint, the Relator Duxbury was a sales representative for Ortho from 1992 to 1998 who was responsible for the promotion and sale in the Western United States of Ortho's blockbuster drug ProCrit approved by the FDA to treat anemia resulting from chemotherapy, chronic kidney disease, HIV infection, and blood loss from certain types of surgery. Pet. 5a. Relator alleged that, beginning in December, 1992 to the 2006 filing date of the amended complaint, Ortho engaged in a scheme to provide kickbacks to health care providers "to induce them to prescribe ProCrit." Pet. 11a. The kickbacks allegedly included "free ProCrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria." Pet.

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[2] Rule 9(b) of the Federal Rules of Civil Procedure provides:

> **Fraud or Mistake; Conditions of Mind.** In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

11a. The Amended Complaint alleged that the kickbacks, among other things, "caused providers and hospitals to submit false claims for payment to Medicare for ProCrit." Pet. 11a. Relator alleged in his initial Complaint, as well as the amended complaint, that he had provided the information to the government prior to filing the suit. Pet. 61a, 30a.

Relator's original Complaint alleging the kickback scheme was filed subsequent to a master consolidated complaint (the "MCC") filed in September, 2002 in a multi-district litigation, *In Re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456, No. 01-12257-PBS (AWP MDL 2002), concerning the fraudulent reporting of the Average Wholesale Price (AWP) of drugs including Ortho's ProCrit. Pet. 6a. The MCC also alleged the use of illegal kickbacks. Pet. 12a. Relator did not allege that he had provided any information concerning his kickback claims to the government *prior to the public disclosure* of the kickback allegations in the MCC. Pet. 16a.

While Relator's case was pending, this Court issued its decision in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007). In *Rockwell*, this Court held that the "information" to which the "original source" exception, §3730(e)(4)(B), speaks is the information upon which the relators' complaint allegations are based and not the information underlying the "public disclosure." Id. at 470-471. This Court based its holding on the fact that "subparagraph (B) standing on its own suggests that disposition" since the statute's plain words require

that the information be provided to the government "*before filing an action*" and that the "information one would expect a relator to 'provide to the Government *before filing an action* . . . based on the information' is the information underlying the relator's claims." Id. at 471.

Subsequent to *Rockwell* the district court in *Duxbury* dealt with Ortho's motion to dismiss on the basis of the "public disclosure bar" and that Duxbury did not qualify as an original source for the kickback scheme because, among other things, Duxbury did not provide the government with the information underlying its complaint prior to the filing of the 2002 MCC in the AWP MDL litigation. Pet. 60a. Ortho also based its motion to dismiss on the assertion that Duxbury's claims were "deficient under Rule 9(b)." Pet. 72a.

The district court found that, although the MCC constituted a "public disclosure" regarding the kickback scheme, Duxbury had "direct and independent knowledge" of the kickback scheme and ruled that the "plain language of [§3730(e)(4)(B)] only requires the relator to provide his information to the government *prior to filing his action*." Pet. 60a. Nevertheless, the district court dismissed Duxbury's kickback scheme claims because, according to the district court, the "Amended Complaint failed to plead the claims with sufficient particularity under Rule 9(b)." Pet. 12a.

On appeal, the First Circuit affirmed the district court's ruling that §3730(e)(4)(B) required Duxbury

to "provide his information to the government prior to filing his action" and *not* "before the public disclosure itself." Pet. 17a. In addition, the First Circuit reversed the district court's dismissal of the claims under Rule 9(b). Pet. 39a.

The First Circuit in affirming the district court's ruling that §3730(e)(4)(B) does not require a relator to provide the information "*prior to the public disclosure*," engaged in an extensive and "careful analysis" of the "original source" exception to the "public disclosure bar" that included a detailed analysis of this Court's decision in *Rockwell*, the structure of the FCA, and the history of the "public disclosure bar." Pet. 16a-30a. The court based its affirmance first and foremost on the "plain and unambiguous" terms of subparagraph B that "only requires the relator to 'provide[ ] the information to the Government *before filing an action* under this section which is based on the information'" and "does not impose any other timing requirement." Pet. 18a. The court therefore, "conclude[d] that the plain terms of §3730(e)(4)(B) begin and end the matter." Pet. 18a.

As a result of Ortho's and the government's claim that relying on the plain and unambiguous language of the statute would lead to "eccentric" results, the First Circuit engaged in an exhaustive analysis of the language and history of the "original source" exception and the "public disclosure bar" and the structure of the FCA to determine if honoring the plain words of the statute would "conflict with the intent of Congress." Pet. 21a. In finding that giving effect to

the plain words of the statute would be consistent with the structure of the FCA and the history of the "original source" exception and the "public disclosure bar," the First Circuit made particular reference to *Rockwell* and the need for "productive private enforcement" of the FCA. Pet. 22a-30a.

The First Circuit noted that *Rockwell* "held that 'information' for purposes of both subparagraphs [A and B] refers to the 'information underlying the allegations of the relator's action' not the information underlying the public disclosure." Pet. 23a. The court pointed out that this important distinction allowed relators "with direct and independent knowledge" of a fraud to "pursue a *qui tam* action under the FCA" where the sources of the "public disclosure" "may fear to come forward." Pet. 24a. The court went on to note that "public disclosure" has the benefit of providing "public pressure on the government to act" in the face of a publicly acknowledged fraud but there were "situations when even that is not enough and the government would benefit from suits brought by relators with substantial information of government fraud even though the outlines of the fraud are in the public domain." Pet. 28a. The court "eschewed reading an exclusion . . . that did not have textual support" and could "discourag[e] productive private enforcement." Pet. 29a. The First Circuit concluded, "the better approach" was "to honor the plain and unambiguous terms of the statute, and hold that §3730(e)(4)(B) only requires that a relator provide

his or her information prior to the filing of the *qui tam* suit." Pet. 30a.

In ruling that Duxbury's kickback claims met the heightened pleading requirements of Rule 9(b) regarding allegations of fraud, the First Circuit specifically found that Duxbury had pleaded with particularity the submission of a representative number of false claims as part of Ortho's alleged nationwide scheme. The First Circuit engaged in a detailed analysis of Duxbury's factual allegations regarding the submission of particular false claims filed by numerous identified medical providers as a result of the alleged kickback scheme. The First Circuit found that Duxbury "set[ ] forth allegations of kickbacks provided by [Ortho] that resulted in the submission of false claims by eight healthcare providers in the Western United States" and that "as to each, Duxbury provides information as to the dates and amounts of the false claims filed by these providers with the Medicare program." Pet. 34a.

The court found, in particular, that Duxbury "alleged the submission of false claims across a large cross-section of providers that alleges the 'who, what, where, and when' of the allegedly false or fraudulent representation": "Duxbury has identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." Pet 36a. The court also found that "Duxbury has also alleged facts with respect to the medical providers he identifies that

support his claim that [Ortho] intended to cause the submission of false claims." Pet 36a. In sum, the court found that "Duxbury has alleged facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide." Pet. 38a. The First Circuit concluded that "the factual evidence alleged here of the submission of false claims caused by [Ortho] at a cross-section of medical providers, is sufficient in this context" and therefore, "Duxbury's allegations pass muster for purposes of Rule 9(b)." Pet. 39a.

REASONS FOR DENYING THE WRIT

I. THERE IS NO ONGOING QUESTION §3730(e)(4)(B) REQUIRES RELATORS TO PROVIDE THEIR INFORMATION *"BEFORE FILING AN ACTION"* AND NOT *"PRIOR TO THE DISCLOSURE"*

There is no ongoing question regarding §3730(e)(4)(B)'s requirement that an "original source" provide their information to the Government *"before filing an action"* and not *"prior to the public disclosure."* Ortho's Petition ignores the fact that whatever confusion existed among the Circuits on this issue was resolved by this Court's decision in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007). Contrary to the suggestions Ortho makes in its Petition, since *Rockwell*, no Circuit has actually premised a decision on the proposition that

§3730(e)(4)(B), despite its plain words, imposes the additional requirement that the information be provided to the Government *"prior to the public disclosure"* and not just *"before filing an action."*

A. *Rockwell* Removed Any Doubt That §3730(e)(4)(B) "Standing On Its Own Suggests Th[e] Disposition" That Relator Is Required To Provide Their Information *"Before Filing An Action."*

This Court in *Rockwell* removed any doubt that, in cases where there has been a public disclosure of an alleged *qui tam* fraud, §3730(e)(4)(B) by its plain terms, requires relators with "direct and independent knowledge" of the fraud to provide their information to the Government *"before filing an action."* In fact, the Court's recognition in *Rockwell* that the plain words of the statute require a relator in cases where there has been a public disclosure of a *qui tam* fraud to provide the information to the Government *"before filing an action"* was integral to the Court's decision in *Rockwell* denying "original source" status to the plaintiff.

In *Rockwell*, this Court dealt with the "original source" exception (§3730(e)(4)(B)) and its requirement that the relator have "direct and independent knowledge of the *information on which the allegations are based.*" The Court dealt with the question of whether §3730(e)(4)(B)'s "phrase 'information on which the allegations are based'" "refer to the information on

which the *relator's allegations* [in his complaint] are based or the information on which the *publicly disclosed allegations* that triggered the public-disclosure bar are based." Id. at 470. The Court noted that the Circuits "had divided over the issue." Id. at 470 fn5.

The Court held that the "information" to which subparagraph (B) speaks that the relator is required to have "direct and independent knowledge" of in order to qualify for the "original source" exception is the information upon which the relators' complaint allegations are based and not the information underlying the "public disclosure." Id. at 470-471. The foundation for the Court's holding that the "information" referred to in §3730(e)(4)(B) is complaint information and not "public disclosure" information are the plain words of the statute requiring that the "information" be provided to the government *"before filing an action."* The Court ruled "subparagraph B standing on its own suggests th[e] disposition" that the "information" is the information underlying the relator's complaint because the "information one would expect a relator to 'provide to the Government *before filing an action* . . . based on the information' is the information underlying the relator's claims":

> To begin with, subparagraph (B) standing on its own suggests that disposition. The relator must have 'direct and independent knowledge of the information on which the allegations are based,' and he must 'provid[e] the information to the Government *before*

> *filing an action* under this section which is based on the information.' Surely the information one would expect a relator to 'provide to the Government *before filing an action* . . . based on the information' is the information underlying the relator's claims.

Rockwell International Corp. v. United States, 549 U.S. 457, 471 (2007) (emphasis added).

The Court in *Rockwell* further demonstrated that §3730(e)(4)(B)'s plain requirement that the relator provide the information "*before filing an action*" was integral to its decision when the Court went on to hold that the "information" referred to in the "original source" exception (subparagraph B) is the same as the "information" referred to in the "public disclosure bar" (subparagraph A) i.e., complaint as opposed to "public disclosure" information. The Court rejected the reasoning of contrary Circuits that had held that the "public disclosure bar" required relators to be the "original source" of the information underlying the "public disclosure" as opposed to the relator's complaint. Id. at 472. It did so by pointing out that the "information" referred to in subparagraph A – that a relator is required to be the "original source" of – is the information of "the person *bringing the action.*" The Court referred back to its "analysis" of subparagraph B and that section's clear reference to "information" provided to the government "*before filing an action.*" "In light of the analysis" it had set forth regarding subparagraph B's plain requirement to provide "information" "*before filing an action*" coupled

with subparagraph A's reference to "information" possessed by the person "*bringing the action*," it was clear to the Court that the "public disclosure bar" and the "original source" exception are both concerned with the relator's relationship to the information *underlying the action* that the relator was "filing"/"bringing" as opposed to the "public disclosure" triggering the need for the relator to qualify as an "original source" of that information:

> The complete phrase at issue [in §3730(e)(4)(A)] is "unless . . . the person *bringing the action* is an original source of the information." It seems to us more likely (*in light of the analysis set forth above*) that the information in question is the information *underlying the action* referred to a few words earlier, to-wit, *the action* "based upon the public disclosure of allegations or transactions" referred to at the beginning of the provision. On this interpretation, "information" in subparagraph (A) and "information on which the allegations are based" in subparagraph (B) are one and the same, viz., information underlying the allegations of the relator's action.

Rockwell International Corp. v. United States, 549 U.S. 457, 472 (2007) (emphasis added except "*underlying the action*" in the original).

Accordingly, the Court made it clear that its entire rationale for holding that *complaint* as opposed to *public disclosure* information is the information that the "original source" must have "direct and

independent knowledge" of, stems from the statute's command that the information be provided "*before filing an action.*" Any suggestion that the unexpressed terms of the statute also required that the "information" be provided "*prior to the public disclosure*" would completely eviscerate the premise of the Court's holding. Under these circumstances, *Rockwell*'s bedrock reliance on the plain words of the statute that the information be provided "*before filing an action*" makes ineluctable that "subparagraph B standing on its own suggests t[he] disposition" that the relator's information has to be provided "*before filing an action*" and not "*prior to the public disclosure.*"

B. Since *Rockwell*, No Circuit Has Based A Decision On §3730(e)(4)(B) Requiring The Relator To Provide His Information "*Prior To The Public Disclosure.*"

Undercutting the proffered rationale for Ortho's Petition is the fact that since *Rockwell* was decided no Circuit has challenged the Court's ruling that §3730(e)(4)(B) "standing on its own" plainly requires that the relator provide his information to the Government "*before filing an action.*" The two post-*Rockwell* cases cited by Ortho from the Sixth and Ninth Circuits, *U.S. ex rel. Poteet v. Medtronic*, 552 F.3d 503 (6th Cir. 2009) and *U.S. ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195 (9th Cir. 2009), do not provide serviceable precedent for Ortho's assertion that there is an ongoing conflict among the

Circuits. Although the two cases, cited by Ortho from the Sixth and Ninth Circuits that post-date *Rockwell*, do reference earlier contrary precedent from those Circuits imposing additional pre-public disclosure requirements on relators that is not found in the plain words of the statute, neither case relies on that precedent for its decision.

In *Poteet*, the Sixth Circuit affirmed the dismissal of a *qui tam* case under the "public disclosure bar." The *Poteet* court in reviewing the statutory requirements qualifying a relator as an "original source" under §3730(e)(4)(B) referenced the Sixth Circuit precedent that predated *Rockwell*, *U.S. ex rel. McKenzie v. BellSouth Telecommunications, Inc.*, 123 F.3d 935 (6th Cir. 1997), that had held "in addition to the requirement that a relator must have provided information to the government prior to filing her FCA suit a relator must also provide the government with the information upon which the allegations are based prior to any public disclosure." *Poteet, supra* at 28-29. However, the court's decision that relator's "*qui tam* complaint is jurisdictionally barred by the FCA's public disclosure provision" was based on the fact that relator "undisputably failed to provide t[he] information to the government *before filing her complaint*" as well as "before the filing" of a third party's complaint that constituted a "public disclosure" of the alleged *qui tam* fraud. *Poteet, supra* at 29. The relator having failed to provide the Government her information "*before filing her complaint*," the *Poteet* court had no need to reach the issue of

whether the relator also had to provide the information *"prior to any public disclosure."* In addition, although it cited to *Rockwell* in referencing the "original source" exception, the *Poteet* court did not discuss *Rockwell* at all regarding the reporting requirements imposed by the statute.

Similarly, in *Meyer*, the Ninth Circuit affirmed the dismissal of a *qui tam* action under the "public disclosure bar." In reviewing the requirements of establishing "original source" status under §3730(e)(4)(B), the *Meyer* court referenced the Ninth Circuit precedent that predated *Rockwell*, *U.S. ex rel. Wang v. FMC Corp.*, 975 F.2d 1412 (9th Cir. 1992), in which the Ninth Circuit held that "to be an original source, a relator 'must satisfy an additional requirement under §3730(e)(4)(A) that is not in the statute *in haec verba*,' namely that he 'had a hand in the public disclosure of the allegations that are a part of his suit.'" *Meyer, supra* at 12. The *Meyer* court however did not need to rely on this precedent because it was clear that "relators lacked the requisite direct and independent knowledge of the alleged fraud to qualify as original sources." Id. As in *Poteet*, the *Meyer* court had no need and did not discuss *Rockwell*'s impact on the previous precedent imposing additional pre-disclosure government reporting requirements under the "original source" exception to the "public disclosure bar."

It is clear then that the two post-*Rockwell* cases cited by Ortho in support of its assertion that there is a "split on when a relator must provide information"

to the Government do not constitute serviceable precedent to support its Petition. In point of fact, the First Circuit is the only Circuit to address this issue head-on since *Rockwell* was decided. There is no reason to believe that the other Circuits, once they have had the appropriate opportunity to do so, will not be compelled, as the First Circuit was, by this Court's focus on the plain language of the "original source" exception and the "public disclosure bar," as well as the history of those provisions and the structure of the FCA, to rule §3730(e)(4)(B) should be taken at its word, to-wit, "[t]he relator . . . must 'provid[e] the information to the Government *before filing an action.*" See *Rockwell, supra* at 471 (emphasis added) and *U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.,* 579 F.3d 13, 21-28 (1st Cir. 2009).

II. THE FIRST CIRCUIT'S 9(b) RULING IS CONSISTENT WITH THE RULINGS OF THE OTHER CIRCUITS REGARDING PLEADING "REPRESENTATIVE EXAMPLES" OF WIDESPREAD FRAUD

In attempting to demonstrate that there is a need for review of the First Circuit's ruling that Duxbury's complaint met the heightened pleading requirements of Rule 9(b), Ortho makes several misleading statements that Duxbury had not identified even one false claim alleged to have resulted

from Ortho's fraudulent nationwide kickback scheme of long duration.[3] This charade was necessary in order to prop up Ortho's contention that the First Circuit applied a less stringent rule that was in conflict with the other Circuits. In point of fact, as the First Circuit's detailed review of Duxbury's allegations makes pellucid, Duxbury "alleged the submission of false claims across a large cross-section of providers that alleges the 'who, what, where, and when' of the allegedly false or fraudulent representation" which "supports a strong inference that such claims were also filed nationwide." Pet. 36a-38a.

With the truth established as to the facts regarding Duxbury's detailed allegations regarding the submission of actual false claims that were a representative cross-section of the nationwide scheme alleged, it is clear that the First Circuit's ruling that Duxbury's complaint passed Rule 9(b) muster is

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[3] Throughout its Petition Ortho makes assertions that misleadingly suggest that Duxbury did not identify any false claims that he alleged were submitted for payment as a result of Ortho's fraudulent kickback scheme: "Questions Presented . . . without identifying a single false or fraudulent claim" (Pet. (i)); "he cannot allege a single specific false claim" (Pet. 20); "for a relator who contends that he lacks the necessary access to specify false claims with particularity" (Pet. 26); "while Duxbury alleged that he was unable to identify 'all of the false claims,' he actually identified none" (Pet. 26 fn4); "He did not plead with particularity any false claims or any false statements or records linked to such claims" (Pet. 30); and, "an FCA plaintiff must allege facts that in some way identify a particular 'false or fraudulent claim.' Duxbury did not do this." (Pet. 33).

completely consistent with the Rule and the standards established by the other Circuits cited by Ortho regarding the pleading requirements for a complex fraudulent scheme of long duration.

Like the First Circuit, the other Circuits cited by Ortho that have considered the issue have held that in "complex" cases alleging a "fraudulent scheme involv[ing] numerous transactions that occurred over a long period of time, the courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct." *U.S. ex rel. Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493, 509-510 (11th Cir. 2007). "The examples that a relator provides will support more generalized allegations of fraud . . . to the extent that the relator's examples are *representative samples* of the broader class of claims." Id. at 510 citing *U.S. ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006) ("Clearly, neither this court nor *Rule 9(b)* requires [a relator] to allege specific details of *every* alleged fraudulent claim forming the basis of [the relator's] complaint. However . . . [the relator] must provide *some* representative examples of [the defendants'] alleged fraudulent conduct, specifying the time, place, and content of their acts and the identity of the actors."), *cert. denied*, 127 S. Ct. 189, 166 L. Ed. 2d 142 (2006). See also, *U.S. ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301, 1314 (11th Cir. 2002) (where "fraud complex" plaintiff has to "allege at least

some examples of actual false claims to lay a complete foundation for the rest of [the] allegations").

It is testimony to the weakness of Ortho's Petition that it has sought to distort the record as to what respondent actually pleaded in order to prop up a contention it believed was more likely to appeal to the Court. As the premise of Ortho's contention is false, i.e., Ortho asserted Duxbury did not allege the submission of any false claims when the truth is he did plead with particularity a representative cross-section of claims evidencing the nationwide scheme, as the First Circuit so found, there is no basis to grant Ortho's Petition regarding the First Circuit's ruling that Duxbury satisfied the heightened pleading requirements of Rule 9(b).

CONCLUSION

The Petition for a writ of certiorari should be denied.

Dated: January 7, 2010

Respectfully submitted,

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IN THE

Supreme Court of the United States

ORTHO BIOTECH PRODUCTS, L.P.,

Petitioner,

v.

UNITED STATES EX REL.
CHINYELU DUXBURY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

SUPPLEMENTAL BRIEF FOR PETITIONER

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QUESTIONS PRESENTED

1. Whether a federal court lacks subject-matter jurisdiction over a *qui tam* suit under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, that repeats publicly disclosed allegations from prior litigation, where the FCA relator did not provide the government with information on the suit's allegations before the public disclosure.

2. Whether an FCA relator, alleging that the defendant induced a third party to submit false or fraudulent claims, can satisfy Rule 9(b) of the Federal Rules of Civil Procedure without identifying a single false or fraudulent claim, but merely by alleging facts sufficient "to strengthen the inference of fraud beyond possibility."

RULE 29.6 DISCLOSURE STATEMENT

The Petitioner, Ortho Biotech Products, L.P. ("OBP"), is a New Jersey corporation and subsidiary of parent corporation Johnson & Johnson, also a New Jersey corporation. No publicly held corporation other than Johnson & Johnson owns 10% or more of OBP's stock.

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SUPPLEMENTAL BRIEF FOR PETITIONER

As its *amicus* brief makes clear, the United States supports the petition in significant respects. The United States agrees that each of the two questions presented concerns a ruling that "deepens an existing conflict" among federal circuits. Br. for the United States as *Amicus Curiae*, No. 09-654, at 9 (May 2010) ("U.S. *Amicus* Br."). It also agrees that the first question has "some continuing practical significance" and could have warranted review in an appropriate case, *id.* at 13, and that this Court's review of the second question "likely would be warranted in an appropriate case," *id.* at 9.

The United States ultimately recommends that the petition should be denied only because of the new healthcare law (the "PPACA").[1] The PPACA, among other things, amended the "original source" provision of the False Claims Act ("FCA"). In the United States' view, that amendment makes the first, "original source" question "not of sufficient continuing importance to warrant . . . review." U.S. *Amicus* Br. at 9. The United States further contends that the change to the "original source" provision renders this case an "[un]suitable vehicle" for resolving the "unsettled and significant" Rule 9(b) question because "the Court could not address the Rule 9(b) issue in this case unless it first determined" the jurisdictional question. *Id.* at 9, 17.

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[1] Patient Protection And Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010).

The United States seriously underestimates the ongoing significance of the first question on "original source." Even after the PPACA, that question potentially affects hundreds of FCA cases—including cases pending when the PPACA was enacted and post-PPACA cases that implicate pre-PPACA conduct. The Court should review the "original source" question as potentially relevant to all of these cases—just as the Court has reviewed questions of similar ongoing significance in the past. *See, e.g.*, *United States v. Centennial Sav. Bank FSB*, 499 U.S. 573, 578 n.3 (1991) (granting certiorari on question about law as it existed before 1986 amendment "in light of the significant number of pending cases concerning the . . . [law] prior to 1986").

The ongoing significance of the "original source" question removes the only U.S. objection to reviewing the Rule 9(b) question. As shown below and contrary to what the United States suggests, because the jurisdictional issue here arises from the FCA statute and not Article III of the Constitution, the Court could also review the Rule 9(b) question even if it decided not to take the "original source" question. The Rule 9(b) question merits review now because, as the United States observes, it is "both unsettled and significant." U.S. *Amicus* Br. at 17. Moreover, notwithstanding the United States' suggestion, another case pending before the Court, *United States ex rel. Hopper v. Solvay Pharms., Inc.*, No. 09-1065 (filed Mar. 4, 2010) ("*Hopper* Pet."), does not present a superior vehicle for addressing the Rule 9(b) question. *See* U.S. *Amicus* Br. at 18 n.6.

I. The Court Should Review The First, "Original Source" Question Because It Is Of Continuing Significance To Hundreds of Pending And Future Cases.

Although the PPACA amended the "original source" provision, the "original source" question still has "continuing practical significance," as the United States acknowledges. U.S. *Amicus* Br. at 13. That is because the "original-source" provision at issue here still applies to hundreds of FCA cases—including (1) those pending when the PPACA was enacted, and (2) those filed post-PPACA that concern pre-PPACA conduct.

First, the "original source" question remains significant to hundreds of FCA cases pending when the PPACA was enacted. According to the Justice Department, 577 FCA cases were "active" as of September 30, 2009. *See* U.S. Dept. of Justice, Civil Div., *Fraud Statistics: Qui Tam Intervention Decisions & Case Status as of Sept. 30, 2009*, final page of *Fraud Statistics – Overview: Oct. 1, 1987 – Sept. 30, 2009, available at* http://www.justice.gov/civil/frauds/fcastats.pdf.[2] Clearly, hundreds of FCA cases were pending when the PPACA was enacted in March 2010. Because the PPACA does not apply retroactively, *see Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010); U.S. *Amicus* Br. at 4, 13 & n.4, the Act's

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[2] This report is available through a link on the Justice Department's *False Claims Act Statistics* webpage, *available at* http://www.justice.gov/civil/frauds/fcastats.html.

amendment to the "original source" provision affects none of these cases, which remain subject to the "original source" provision at issue here.

Second, the "original source" question remains relevant also to cases filed *after* the PPACA's enactment. As this Court made clear in *Hughes Aircraft Co. v. United States ex rel. Schumer*, an amendment to the "original source" provision that Congress did not make expressly retroactive and that removes a defense—like the PPACA amendment—does not apply retroactively. 520 U.S. 939, 946-48 (1997). And a provision that is not retroactive does "not apply to the conduct . . . which occurred prior to [the amendment's] effective date." *Id.* at 946. Because the pre-PPACA "original source" provision will apply to future suits that challenge conduct occurring before the PPACA's enactment, the first question remains relevant to all of these suits as well.

The Court should thus review the first question presented because it is of continuing importance to hundreds of FCA cases. *See Centennial Sav. Bank FSB*, 499 U.S. at 578 n.3 (granting certiorari on question about law as it existed before 1986 amendment "in light of the significant number of pending cases concerning the . . . [law] prior to 1986").

II. The Court Should Review the Second, Rule 9(b) Question Because It Is Unsettled And Significant.

A. The Court Should Reach The Rule 9(b) Question After Deciding The "Original Source" Question.

The Court should also review the second, Rule 9(b) question. The United States agrees that the question implicates a "deep[]" circuit conflict on an "unsettled and significant" issue and thus "likely" warrants this Court's review in an "appropriate" case.[3] U.S. *Amicus* Br. at 9, 17. And the continuing significance of the "original source" question, as shown above, renders unpersuasive the United States' only objection to reviewing the Rule 9(b) question in this case. *Id.* at 9, 17-18.

Moreover, this Court often addresses threshold jurisdictional questions before reaching a question on the merits. Just last term, in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), this Court granted certiorari to

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[3] On the merits, the United States argues (U.S. *Amicus* Br. at 17) that a Rule 9(b) standard that would require the relator to identify false claims should be rejected because it would deter relators with helpful information about alleged fraud from filing suit. The United States' policy argument is untethered to either the text of Rule 9(b) or the purposes it is designed to serve. *See* Pet. for a Writ of Cert., *Ortho Biotech Prods., L.P. v. United States ex rel. Duxbury*, No. 09-654, at 31 (Dec. 3, 2009) ("OBP Pet."); Reply Brief for Petitioner, *Ortho Biotech Prods., L.P. v. United States ex rel. Duxbury*, No. 09-654, at 11-12 (Jan. 20, 2010) ("OBP Reply Br.").

address a federal pleading standard question in the face of an argument that the case was an unsuitable vehicle because a question existed about the Court's jurisdiction. The Court went on to decide the jurisdictional question, which enabled it to reach the pleading standard issue. *Id.* at 1945.

B. The Court Could Also Review The Rule 9(b) Question On Its Own.

Furthermore, contrary to the United States' contention (U.S. *Amicus* Br. at 9, 17-18), the Court need not decide the "original source" question in order to review the question on Rule 9(b). Although the "original source" question is jurisdictional, it concerns *statutory*, not Article III, jurisdiction. Courts may defer statutory jurisdiction questions to reach other questions—including merits questions—that enable them to dispose of the issue at hand. *See, e.g., Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 97 n.2 (1998) (acknowledging that courts can prioritize merits questions over statutory standing questions); *Conyers v. Rossides*, 558 F.3d 137, 150 (2d Cir. 2009) (declining to decide whether statute divests the court of jurisdiction and "proceed[ing] to address the alternative argument for dismissal" under Fed. R. Civ. P. 12(c) (judgment on the pleadings), where "the question is one of statutory rather than constitutional jurisdiction"); *Chalabi v. Hashemite Kingdom of Jordan*, 543 F.3d 725, 728 (D.C. Cir. 2008) ("*Steel Co.* requires that we prioritize the jurisdictional issue only when the existence of *Article III* jurisdiction is in doubt; that decision explicitly recognized the propriety of addressing the merits where doing so made it possible to avoid a doubtful issue of *statutory*

jurisdiction.") (internal quotation marks and citation omitted); *Guaylupo-Moya v. Gonzales*, 423 F.3d 121, 132 n.10 (2d Cir. 2005) (declining to resolve question of statutory jurisdiction before disposing of *ex post facto* argument on the merits); *United States ex rel. Wood v. Applied Research Assocs., Inc.*, 328 Fed. Appx. 744, 746 (2d Cir. 2009) (unpublished) ("Because we agree that [the FCA relator's] claims fall short of the pleading standard required by Fed. R. Civ. P. 9(b), . . . we decline to reach the question of whether the district court had subject matter jurisdiction under 31 U.S.C. § 3730(e)(4)(A)."), *cert. denied*, 130 S. Ct. 1285 (2010).

Here, if this Court were to bypass the statutory jurisdiction question to reach the Rule 9(b) question, it would alter the posture of the case *only* if it ruled that dismissal for failure to satisfy 9(b) was warranted, but dismissal is precisely the result that would obtain from a finding of no jurisdiction. Bypassing the statutory jurisdiction question thus would not "take the [C]ourt into vast, uncharted realms of judicial opinion giving." *Steel Co.*, 523 U.S. at 97 n.2.

For all of these reasons, and contrary to the argument of the United States, this case is not a poor vehicle for resolving the Rule 9(b) question.

III. The *Hopper* Case Is Not A Better Vehicle For Resolving The Rule 9(b) Question.

The United States suggests that another case pending before the Court, *Hopper*, may be a better vehicle for addressing the Rule 9(b) question presented by Petitioner. *See* U.S. *Amicus* Br. at 18 n.6. Here too, the United States is mistaken.

First, the questions presented in the two petitions are not the same. This petition's Rule 9(b) question (and the court of appeals' decision) covers *both* core FCA liability provisions—31 U.S.C. §§ 3729(a)(1) and (a)(2).[4] The *Hopper* question expressly concerns only Section 3729(a)(2). *See Hopper* Pet. at i (question presented referencing only 31 U.S.C. § 3729(a)(2)).

Second, this petition's Rule 9(b) question concerns "[w]hether an FCA relator, alleging that the defendant induced a third party to submit false or fraudulent claims, can satisfy Rule 9(b) . . . without identifying a single false or fraudulent claim, but merely by alleging facts sufficient to strengthen the inference of fraud beyond possibility." OBP Pet. at i (internal quotation marks omitted). It thus concerns not only whether Rule 9(b) requires FCA relators to identify false or fraudulent claims but also, more basically, what Rule 9(b) *measures—i.e.*, whether it measures *plausibility* and perhaps requires only allegations that make fraud more than possible, or whether it measures *particularity* in a way that adds something to the Rule 8 plausibility standard. *See, e.g.*, OBP Pet. at 24-26, 32-33; OBP Reply Br. at 8 (Jan. 20, 2010).[5] By contrast, the *Hopper* question

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[4] These provisions were renumbered and amended by the Fraud Enforcement And Recovery Act Of 2009, Pub. L. No. 111-21, 123 Stat. 1617, 1621-23 (May, 20, 2009) ("FERA"). As previously noted, and as neither respondent nor the United States disputes, the changes do not affect the Rule 9(b) question presented. *See* OBP Pet. at 3 n.1; OBP Reply Br. at 9 n.2.

[5] The United States appears to agree with the First Circuit that the Rule 9(b) standard requires nothing more than Rule 8 in (continued...)

concerns only "[w]hether Rule 9(b) . . . requires the identification of a specific false claim." *Hopper* Pet. at i.

Third, the *Hopper* case is not a good vehicle to decide whether a relator needs to identify a specific false claim even under Section 3729(a)(2), because the Eleventh Circuit expressly stated that it was *unnecessary* to decide that question because the complaint failed to allege adequately the element of *intent*. *See Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1330-31 (11th Cir. 2009); Br. in Opp'n to Pet. for Writ of Cert., *Hopper*, No. 09-1065, 2010 WL 1900659, at *7-8 (May 10, 2010) (arguing that the Eleventh Circuit's decision addressed only Rule 9(b)'s application to allegations of intent).

Finally, while the United States notes that *Hopper* "does not appear to contain any potential jurisdictional obstacle," U.S. *Amicus* Br. at 18 n.6, we have explained above why the statutory jurisdiction question should not be viewed as an "obstacle" to further review.

For all of these reasons, this petition is a better vehicle than *Hopper* for addressing Rule 9(b)'s application to the core liability provisions of the FCA.

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the FCA context. *See* U.S. *Amicus* Br. at 14-15 (stating that the First Circuit's holding that a relator can satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility" is "correct") (internal quotation marks and citations omitted).

IV. If The Court Does Not Review The Rule 9(b) Question, It Should Hold This Case Until It Disposes Of The Question In *Hopper*.

While this case is a better vehicle than *Hopper* to address the Rule 9(b) question presented here, the *Hopper* question—as to whether or not "Rule 9(b) . . . requires the identification of a specific false claim," *Hopper* Pet. at i—is undeniably relevant to the court of appeals' holding at issue here. Petitioner thus requests, if the Court decides to review the Rule 9(b) question presented in *Hopper* rather than in this case, that the Court defer its disposition of this petition until it resolves the related question presented in *Hopper*.

CONCLUSION

The petition for a writ of certiorari should be granted. In the alternative, if the *Hopper* petition is granted, this petition should be held and disposed of in accordance with the resolution in *Hopper*.

Respectfully submitted,

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June 1, 2010

No. 09-654

IN THE

Supreme Court of the United States

ORTHO BIOTECH PRODUCTS, L.P.,

Petitioner,

v.

UNITED STATES EX REL.
CHINYELU DUXBURY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

REPLY BRIEF FOR PETITIONER

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January 20, 2010

RULE 29.6 DISCLOSURE STATEMENT

The Petitioner, Ortho Biotech Products, L.P. ("OBP"), is a New Jersey corporation and subsidiary of parent corporation Johnson & Johnson, also a New Jersey corporation. No publicly held corporation other than Johnson & Johnson owns 10% or more of OBP's stock.

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REPLY BRIEF FOR PETITIONER

Respondent misinterprets this Court's decision in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007), as resolving a circuit split on when a relator must provide the government with information supporting his suit's allegations to qualify as an original source. This split persists post-*Rockwell*, as evidenced by the Sixth and Ninth Circuits' continued reliance on pre-*Rockwell* precedents. Because "proper application of the [False Claims Act's ("FCA's")] public disclosure bar is critical to enforcement of that statute," Brief for the United States as Amicus Curiae, *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, No. 08-1409, at 3 (Aug. 28, 2008) ("United States Brief"), this Court should decide the issue now.

On Rule 9(b), Respondent does not even attempt to defend the First Circuit's "more flexible [pleading] standard" (Pet. App. 35a) for relators alleging that a "defendant induced *third parties* to file false claims with the government" (*id.* at 32a). Respondent contends instead that the Complaint here alleged "representative examples of false claims" (Opp. 3) and thus satisfied the stricter Rule 9(b) standard applied by other courts of appeals.

Respondent's refusal to defend the First Circuit's Rule 9(b) standard is not surprising, because, as explained in the Petition (pp. 24-26, 32), that standard is no more demanding than the Rule 8 notice pleading standard as construed by this Court in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). And Respondent's assertion that the Complaint satisfied the stricter standard applied by other circuits is

plainly wrong. Contrary to Respondent's contentions, and as the First Circuit itself recognized, the Complaint identified *not one* false claim, much less a representative sample of such claims. Pet. App. 36a ("Duxbury does not identify specific claims.").

This case—in which the First Circuit held that Duxbury's satisfaction of its "more flexible standard" was "a close call" (Pet. App. 35a)—therefore presents an ideal vehicle for this Court to decide whether an FCA relator can satisfy Rule 9(b) without providing details about a single false or fraudulent claim, but merely by alleging facts sufficient "to strengthen the inference of fraud beyond possibility." *Id.* at 33a (internal quotation marks omitted). This "relaxed" Rule 9(b) standard—oddly available to relators *not* in a position to know whether false claims were actually filed, including the original relator here[1]—will only encourage more meritless and costly qui tam suits.

I. The Court Should Resolve A Circuit Split, Persisting After *Rockwell*, On When An Original Source Must Inform The Government Of Alleged Fraud.

1. Respondent contends (Opp. 11-19) that further review on the "original source" question is unwarranted because this Court in *Rockwell* purportedly resolved the circuit conflict on the issue.

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[1] On December 10, 2009, the district court allowed Chinyelu Duxbury to substitute as relator for her deceased spouse, original relator Mark Duxbury.

In *Rockwell*, however, this Court *expressly refused* to decide when an original source must inform the government of alleged fraud. *See* 549 U.S. at 476 ("Because [relator] did not have direct and independent knowledge of the information upon which his allegations were based, we need not decide whether [relator] met the second requirement of original-source status, that he have voluntarily provided the information to the Government before filing his action.").

Respondent is thus compelled to argue that *Rockwell* implicitly decided that an original source need not provide his information to the government before a public disclosure. Respondent contends that, in holding that the "information" about which an original source must have "direct and independent knowledge" is "complaint information and not 'public disclosure' information," the *Rockwell* Court relied on "the plain words of the statute requiring that the 'information' be provided to the government '*before filing an action.*'" Opp. 13. The *Rockwell* language italicized by Respondent, however, merely repeats statutory text known long before *Rockwell* by every court split over the "original source" issue presented here. And the fact that an original source must have direct and independent knowledge of the information underlying his action simply does not answer whether he must provide that information to the government before a public disclosure. As the United States explained post-*Rockwell*, requiring "a relator [to] come forward prior to a public disclosure best advances the FCA's twin goals of alerting the Government to potential fraud and creating incentives for relators to do so at the earliest possible time." United States Brief, at 23.

2. Because *Rockwell* did not resolve, expressly or implicitly, the "original source" question presented here, there is no reason to require special evidence that a circuit split on the issue persists post-*Rockwell*, as Respondent suggests. *See* Opp. 16-19. In any event, contrary to Respondent's assertions, post-*Rockwell* cases demonstrate that the split persists. Respondent acknowledges (Opp. 17-18) that Sixth and Ninth Circuit post-*Rockwell* cases—*i.e.*, *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503 (6th Cir. 2009), and *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195 (9th Cir. 2009)—restate positions that conflict with the First Circuit's holding on the "original source" issue. Respondent argues, however, that those decisions "do not provide serviceable precedent" (Opp. 16) perpetuating the conflict post-*Rockwell*, because the courts relied on pre-*Rockwell* interpretations of the "original source" provision only in dicta. Respondent is incorrect.

In *Meyer*, after citing *Rockwell*, the Ninth Circuit held that the district court did not err in denying relators "original source" status, 565 F.3d at 1201-03, *both* because the relators lacked "direct and independent knowledge" *and* because they had no "hand in the public disclosure of those allegations," *id.* at 1203—something they had to have if they informed the government of the alleged fraud after the public disclosure. Neither of those alternative bases for decision has any priority over the other and thus neither is dicta. "[W]here a decision rests on two or more grounds, none can be relegated to the category of obiter dictum." *Woods v. Interstate Realty Co.*, 337 U.S. 535, 537 (1949). *See also MacDonald, Sommers & Frates v. Yolo County*, 477 U.S. 340, 346

n.4 (1986) ("two stated reasons" for holding are "alternative bases of decision," not dicta).

The Sixth Circuit's *Poteet* decision similarly perpetuates the conflict. After citing *Rockwell*, the court concluded that the relator could not be an original source *both* because she did not inform the government of her allegations before filing suit *and* because she did not inform the government of the alleged fraud before its public disclosure. *See* 552 F.3d at 515.

The United States, the real party in interest in FCA cases, also remains, post-*Rockwell*, opposed to the First Circuit's approach. *See* United States Brief, at 22-24. *Rockwell* did not resolve the question presented, and seven circuits along with the United States remain split on the issue. *See* Pet. 16-21; *see also* John T. Boese, *Civil False Claims and Qui Tam Actions* § 4.02[D], at 4-114 (3d ed. 2009) (noting post-*Rockwell* "deep divisions" among circuits on "original source" question presented here).

3. It is clear, moreover, that the First Circuit's interpretation is incorrect. Respondent does not deny that, contrary to congressional intent, under the First Circuit's approach relators like Duxbury who piggyback on public disclosures and are thus not true "whistleblowers" can pursue an FCA action and demand a substantial share of any government recovery. *See* Pet. 22-23. Nor does Respondent deny that the First Circuit's approach makes requiring that an "original source" inform the government of alleged fraud of no practical effect. Another FCA provision, 31 U.S.C. § 3730(b)(2) (2006), already requires *all* relators to do that upon filing suit. *See* Pet. 23-24. The United States correctly construes

the "original source" exception, like the Sixth and D.C. Circuits, as requiring an original source to "disclose his information to the Government prior to a public disclosure." United States Brief, at 24.

II. The Court Should Review The First Circuit's Rule 9(b) Standard, Which Conflicts With Decisions Of This Court And Other Circuits And Encourages Meritless FCA Suits.

Respondent does not defend the First Circuit's "more flexible" Rule 9(b) standard, under which relators such as Duxbury need not plead specific details of any false claims but only allegations that "strengthen the inference of fraud beyond possibility." Pet. App. 33a. Instead, Respondent contends (Opp. 3) that the First Circuit used a different standard, consistently applied by other circuits, that requires pleading with particularity "representative examples" of false claims. Respondent is incorrect. The First Circuit plainly held that Duxbury's allegations passed muster only under its "more flexible standard." The decision thus provides this Court an excellent vehicle for reviewing the clear conflict between that standard and (1) this Court's precedents construing Rule 8 and (2) the approaches of other circuits that, as Respondent concedes (Opp. 3), require specifying "representative examples" of false claims.

1. Respondent contends that Petitioner "misleadingly suggest[ed]" that Duxbury did not identify any false claims (Opp. 2), but the First Circuit *expressly found* that he did not do so: "Duxbury does not identify specific claims." Pet. App. 36a. The First Circuit faulted the district court for requiring Duxbury to do so, explaining that there

is "a distinction between a qui tam action alleging that the defendant made false claims to the government, and a qui tam action in which the defendant induced *third parties* to file false claims." *Id.* at 32a (citation omitted). The First Circuit asserted that in cases involving "the latter context," such as Respondent's, the relator can satisfy Rule 9(b) merely "by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility'" without identifying false claims. *Id.* at 33a (internal quotation marks omitted).

The First Circuit then applied this "more flexible standard" and concluded that Duxbury's satisfaction of it was "a close call." Pet. App. 35a. The court asserted that Duxbury, while failing to "identify specific claims," provided enough "specifics" about Petitioner's alleged scheme—including the nature of the scheme (alleged kickbacks in the form of free drug samples and undisclosed rebates), the identity of some third parties who allegedly received kickbacks, and "the rough time periods" of the scheme, *id.* at 36a—"to strengthen the inference of fraud beyond possibility." *Id.* at 38a (internal quotation marks omitted). In so holding, the First Circuit highlighted as "instructive" an allegation that identified a facility that allegedly received free drug samples, while providing no details of any individual claim submitted as a result of the alleged "kickback." Pet. App. 35a (quoting Am. Compl. ¶ 211d). While the First Circuit concluded that allegations like this one sufficed to trigger an "inference of fraud beyond possibility," *id.* at 38a, they do not qualify as pleading a false claim with particularity. *See, e.g.*, *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir.

2006) (conclusory allegations insufficient for Rule 9(b)).

2. Thus, contrary to Respondent's contention (Opp. 3, 19-22), the First Circuit held that Duxbury satisfied its "more flexible [Rule 9(b)] standard," notwithstanding his *failure* to "identify specific [false] claims," Pet. App. 36a, much less a "representative cross-section of claims," Opp. 22. This standard wrongly measures the adequacy under Rule 9(b) of a relator's allegations based upon their *plausibility*, not their *particularity*. As explained in the Petition, *see* pp. 24-26, 32, that standard collapses Rule 9(b) into Rule 8, and thereby conflicts with this Court's precedent distinguishing Rule 9(b)'s heightened standard from Rule 8. *See Iqbal*, 129 S. Ct. at 1949, 1954; *Twombly*, 550 U.S. at 555-57. The First Circuit's adoption for FCA cases of a "flexible" Rule 9(b) standard no more stringent than "the less rigid . . . strictures of Rule 8," *Iqbal*, 129 S. Ct. at 1954, merits this Court's review.

3. The First Circuit's "flexible" standard also conflicts with the approach of other circuits that demand that relators provide details about actual false claims. The day after the petition was filed here, the Eleventh Circuit held that allegations that a defendant caused third parties to file false claims, in violation of 31 U.S.C. § 3729(a)(1), were deficient under Rule 9(b) because they did not "allege dates, times, or amounts of *individual* false claims" and "Rule 9(b) requires that *actual presentment of a claim* be pled with particularity." *Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1326-27 (11th Cir. 2009) (emphases added). That holding squarely conflicts with the First Circuit's "more flexible

standard" for relators alleging that a defendant caused a third party to submit false claims.[2]

The Sixth and Eighth Circuits similarly require allegations identifying particular false claims and reject relaxing Rule 9(b) for relators lacking knowledge of, or access to, the billing practices of the party who allegedly submitted them. In *United States ex rel. Bledsoe v. Community Health Sys., Inc.*, the Sixth Circuit "h[e]ld that pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)." 501 F.3d 493, 504 (6th Cir. 2007). While the Sixth Circuit explained that

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[2] In discussing what Rule 9(b) requires for allegations under 31 U.S.C. § 3729(a)(2) (2006), the Eleventh Circuit distinguished the First Circuit's decision here by asserting that Duxbury's intent allegations seemed more particularized. *See Hopper*, 588 F.3d at 1330-31. As noted in the Brief of Washington Legal Foundation as Amicus Curiae in Support of Petitioner, No. 09-654 (Jan. 4, 2010) ("WLF Brief"), at 13 n.3, that "does nothing to lessen the conflict" underlying the question presented here, which is whether a relator must allege particularized *false claims* under 31 U.S.C. § 3729(a)(1) and (2) (2006). The Court's resolution of that question as to § 3729(a)(1) would apply equally to its successor provision, § 3729(a)(1)(A) (2009), both of which create liability for knowingly causing the submission of false claims, and the Court's resolution as to § 3729(a)(2) would apply equally to its successor provision, § 3729(a)(1)(B) (2009), both of which require a "false statement or record" linked to a "false or fraudulent claim." *See* Pet. 3 n1. The FCA amendment in the Fraud Enforcement And Recovery Act Of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (May 20, 2009), thus does not affect the importance of the Rule 9(b) question presented here.

relators pleading "complex and far-reaching fraudulent scheme[s]" need not identify "every false claim," the court held that they must "provide[] examples of specific false claims submitted to the government . . . representative . . . of the broader class of claims . . . to proceed to discovery on a fraudulent scheme." *Id.* at 510 (emphasis omitted). *See also United States ex rel. Lacy v. New Horizons, Inc.*, Civ. No. 08-6248, 2009 WL 3241299, at *3 (10th Cir. Oct. 9, 2009) (unpublished) (affirming dismissal of FCA claim for failing to allege a "single instance of a particular false claim . . . representative of the class described").

The Sixth Circuit, contrary to the First, also expressly rejected relaxing Rule 9(b) when "third parties possess information concerning the specific contracts at issue and the claims submitted for payment." *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003). The court explained that relaxing Rule 9(b) in FCA cases is unnecessary to protect the public "because the government's ability to intervene on the basis of information brought to its attention vindicates the public interest." *Id.* at 563. Indeed, because the government either possesses the relevant billing information or could obtain it, *see* WLF Brief, at 16 & n.4, the First Circuit's apparent justification for relaxing Rule 9(b) for a substantial category of relators lacks merit.

The Eighth Circuit similarly held that while relators need not provide "specific details of *every* alleged fraudulent claim" to satisfy Rule 9(b), they "must provide *some* representative examples." *Joshi*, 441 F.3d at 557.

Moreover, the Eighth Circuit in *Joshi* flatly rejected the relator's request to relax Rule 9(b) as the First Circuit did here. While recognizing that "the nature of Dr. Joshi's position with St. Luke's as an anesthesiologist, rather than as a member of St. Luke's billing or claims department, may not have made him privy to certain details relevant to his complaint and helpful to satisfying Rule 9(b)," the court held that "neither the Federal Rules nor the FCA offer any special leniency under these particular circumstances to justify Dr. Joshi failing" to meet the traditional Rule 9(b) standard. *Joshi*, 441 F.3d at 560 (brackets and internal quotation marks omitted). In rejecting the First Circuit's approach, under which relators such as Duxbury who lack first-hand knowledge of a third party's billing practices are exempted from the traditionally strict Rule 9(b) test, the Eighth Circuit noted the perversity of relaxing the test for someone, like Duxbury, claiming to have "direct and independent knowledge" of alleged fraud. *Id.* (citation omitted).

4. This Petition enables the Court to resolve conflicts over what Rule 9(b) requires for FCA suits. Rule 9(b) serves an important gate-keeping function in cases "understood to raise a high risk of abusive litigation," *Twombly*, 550 U.S. at 569 n.14—a function especially critical in FCA cases, where a plaintiff may pursue potentially breathtaking sums without having to show any injury. The threat of harassing "strike suits" and "fishing expeditions," *see Bledsoe*, 501 F.3d at 510, is thus particularly high in FCA cases, of which there recently has been "a surge." Brief Amicus Curiae of the American Hospital Association in Support of Petitioner, No. 09-654 ("AHA Brief"), at 20-21. The First Circuit's

"flexible standard" eviscerates Rule 9(b)'s mechanism for barring meritless but expensive and reputation-harming suits, which increasingly subject pharmaceutical companies and health care providers dealing with complex regulatory schemes to burdensome discovery and potentially ruinous liability. AHA Brief, at 20-22; WLF Brief, at 13-18. Petitioner should not have to suffer the harms Rule 9(b) is designed to prevent on the paradoxical ground that a relator professing to have "direct and independent knowledge" of FCA violations lacks information necessary to plead false claims with particularity.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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No. 09-654

In the Supreme Court of the United States

ORTHO BIOTECH PRODUCTS, L.P., PETITIONER

v.

UNITED STATES, EX REL. CHINYELU DUXBURY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

1. Whether a relator in a *qui tam* action under the False Claims Act, 31 U.S.C. 3729 *et seq.*, must provide the government with information about his allegations of fraud before the public disclosure of those allegations occurs in order to qualify as an "original source" under 31 U.S.C. 3730(e)(4)(B).

2. Whether a relator must identify specific false claims submitted for payment to the government in order to plead fraud with sufficient particularity to satisfy Federal Rule of Civil Procedure 9(b).

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In the Supreme Court of the United States

No. 09-654

ORTHO BIOTECH PRODUCTS, L.P., PETITIONER

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UNITED STATES, EX REL. CHINYELU DUXBURY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

INTEREST OF THE UNITED STATES

This brief is submitted in response to this Court's invitation to the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. The False Claims Act (FCA), 31 U.S.C. 3729 *et seq.*, provides for the imposition of civil penalties and treble damages against any person who, *inter alia*, "knowingly presents, or causes to be presented, to an officer or employee of the United States Government * * * a false or fraudulent claim for payment or approval." 31 U.S.C. 3729(a)(1). The Attorney General may bring a civil action if he finds that a person has committed a violation. 31 U.S.C. 3730(a). Alternatively, a private person (known as a relator) may bring his own

suit (commonly referred to as a *qui tam* action) "for the person and for the United States Government." 31 U.S.C. 3730(b)(1); see *United States ex rel. Eisenstein* v. *City of New York*, 129 S. Ct. 2230, 2232 (2009) (quoting 31 U.S.C. 3730(b)(1)).

If a relator brings a *qui tam* action, the complaint is initially filed under seal and served upon the government, together with "substantially all material evidence and information the [relator] possesses." 31 U.S.C. 3730(b)(2). "The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information," *ibid.*, and the district court may extend the 60-day period upon a showing of good cause, 31 U.S.C. 3730(b)(3). If the government declines to intervene, the relator "shall have the right to conduct the action," but the district court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C. 3730(c)(3). If a *qui tam* action results in the recovery of damages or civil penalties, the award is divided between the government and the relator. 31 U.S.C. 3730(d).

Until recently, the FCA's "public disclosure" provision stated:

> (4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office [(GAO)] report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. 3730(e)(4) (footnote omitted); see *Hughes Aircraft Co.* v. *United States ex rel. Schumer*, 520 U.S. 939, 944, 946 (1997). This version of 31 U.S.C. 3730(e)(4) establishes a non-waivable limitation on the subject-matter jurisdiction of the federal courts. *Rockwell Int'l Corp.* v. *United States*, 549 U.S. 457, 467-470 (2007).

On March 23, 2010, however, the President signed into law the Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119. The PPACA amends the FCA's "public disclosure" provision, including its definition of the term "original source." Specifically, Section 10104(j)(2) of the PPACA amends 31 U.S.C. 3730(e)(4) to provide as follows:

> (4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media, unless the action is brought by the Attorney General or the person

> bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (ii) has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

See *Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010) (*Graham County*) (noting the legislative change).

The Court in *Graham County* stated that the PPACA "makes no mention of retroactivity, which would be necessary for its application to pending cases given that it eliminates [the defendants'] claimed defense to a *qui tam* suit." 130 S. Ct. at 1400 n.1; see *Hughes Aircraft*, 520 U.S. at 945-952 (declining to give retroactive effect to FCA amendment that expanded the range of circumstances in which *qui tam* suits could be filed). The first question presented in this case, which involves the application of the FCA's "public disclosure" provision to respondent's complaint, therefore continues to be governed by the pre-PPACA version of 31 U.S.C. 3730(e)(4).

2. Petitioner Ortho Biotech Products, L.P., markets and distributes Procrit, a drug that is used to treat patients with severe anemia. In November 2003, respondent Mark Duxbury, who worked for petitioner from 1992 to 1998, brought a *qui tam* action under the FCA. Respondent alleged that petitioner had been engaged

since 1992 in an unlawful scheme to promote the use of Procrit, which in turn had caused medical providers to submit false claims to federal health insurance programs including Medicare. Specifically, respondent alleged that petitioner had inflated its published "average wholesale price" (AWP) of Procrit, which is the price used by Medicare for reimbursement; had marketed Procrit at a lower price, allowing medical providers to profit on the difference between the AWP and the actual price; had given other kickbacks to medical providers in order to induce them to purchase Procrit; and had promoted off-label uses of Procrit. Pet. App. 5a-7a.

Respondent's *qui tam* action was not the first suit premised on such allegations. In September 2002, other plaintiffs had filed a consolidated complaint in multidistrict litigation, alleging that petitioner and other pharmaceutical companies had inflated the published AWPs for many of their prescription drugs. Pet. App. 5a-6a; see *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 176 (D. Mass. 2003). That action, like the present suit, also alleged that pharmaceutical companies including petitioner had offered kickbacks to medical providers in order to induce them to purchase prescription drugs. Pet. App. 53a.

In April 2004, the government requested in writing that respondent provide additional information about the allegations in his complaint. In July 2004, respondent provided a written disclosure of that information. In July 2005, the government declined to intervene in the suit, leaving respondent to conduct the action. In October 2006, respondent amended his complaint. As relevant here, in Count 1 of his amended complaint, respondent alleged that petitioner had provided kickbacks

to medical providers, thereby inducing them to purchase Procrit and to submit false claims for payment of the inflated AWP to Medicare. Pet. App. 9a-11a.[1]

3. On January 28, 2008, the district court granted petitioner's motion to dismiss the complaint with prejudice. Pet. App. 44a-78a.

a. The district court held that it had jurisdiction to consider respondent's kickback claim. In the court's view, that claim was "based upon the public disclosure of allegations" in a "civil * * * hearing," 31 U.S.C. 3730(e)(4)(A), namely, the similar kickback allegations in the AWP multidistrict litigation. Pet. App. 59a. The court held, however, that respondent had "independent and direct" knowledge, and therefore was an "original source," with regard to the complaint's "allegations concerning the 1992-1998 time period" when he was employed by petitioner. *Id.* at 61a.

Petitioner argued that respondent did not qualify as an "original source" because he had not provided the government with the information upon which his suit was based prior to the public disclosure. Pet. App. 60a. The district court rejected that contention. The court stated that "[t]he plain language of [31 U.S.C. 3730(e)(4)(B)] only requires the relator to provide his information to the government prior to filing his action,"

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[1] Respondent's amended complaint contained two other counts that are not at issue here. Count 2 alleged that petitioner had engaged in a scheme to inflate Procrit's AWP. The parties subsequently stipulated to dismissal of Count 2. Pet. App. 10a n.5. Count 3 alleged that petitioner had promoted off-label uses that involved higher doses of Procrit, thus accelerating the rate at which false claims for payment were submitted to Medicare. *Id.* at 10a-11a. The district court dismissed Count 3 as barred by an earlier *qui tam* action, the court of appeals affirmed that portion of the district court's order, and respondent has not sought review of that decision in this Court. *Id.* at 43a.

ibid., and it explained that respondent had "alleged in his initial complaint instigating the action that he had provided the information to the government prior to filing the suit," *id.* at 61a.

b. The district court held, however, that respondent's suit should be dismissed because his complaint failed to plead fraud with sufficient particularity to satisfy Federal Rule of Civil Procedure 9(b). The court acknowledged that respondent's amended complaint "alleges particularized details about [petitioner's] underlying scheme to induce doctors to prescribe Procrit by granting them a variety of kickbacks." Pet. App. 73a. The court stated, however, that the complaint does not contain "particularized allegations regarding the false claims that were actually submitted to the federal government." *Ibid.* The court concluded that, because respondent had failed "to identify a single false claim" submitted by medical providers, the complaint lacked the particularity required by Rule 9(b) and circuit precedent. *Id.* at 75a-77a (citing *United States ex rel. Karvelas* v. *Melrose-Wakefield Hosp.*, 360 F.3d 220, 232-233 (1st Cir.), cert. denied, 543 U.S. 820 (2004)).

4. The court of appeals affirmed in part and reversed and remanded in part. Pet. App. 1a-43a.

a. The court of appeals affirmed the district court's holding that respondent was an "original source" within the meaning of 31 U.S.C. 3730(e)(4)(B) because he had provided the government with his information before filing suit. Pet. App. 16a-17a.[2] The court recognized that, under the construction of Section 3730(e)(4)(B) adopted by some other circuits, the relator must be the

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[2] Respondent did not dispute that his kickback claim was based upon the public allegations in the AWP multidistrict litigation. Pet. App. 15a.

source of the public disclosure or provide his information to the government prior to the public disclosure in order to qualify as an "original source." *Ibid.* But the court rejected those requirements as inconsistent with "the plain terms of [Section] 3730(e)(4)(B)," *id.* at 18a, which require the relator to "provide[] the information to the Government before filing an action," 31 U.S.C. 3730(e)(4)(B). See Pet. App. 18a-21a. The court of appeals also examined the structure and history of Section 3730(e)(4) and found that they further supported the court's construction of the term "original source." *Id.* at 22a-30a.

b. The court of appeals reversed the district court's holding that respondent had failed to plead his kickback claim with sufficient particularity. Pet. App. 32a. The court explained that a relator can "satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." *Id.* at 33a (quoting *United States ex rel. Rost* v. *Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)). Applying that standard, the court noted that respondent had named eight medical providers who had allegedly provided false claims. *Id.* at 34a-35a. In addition, respondent had supplied the approximate "dates and amounts of the false claims filed by these providers with the Medicare program." *Id.* at 35a. The court concluded that, by providing those details about the false claims that petitioner had caused to be submitted, respondent had alleged with sufficient particularity "that false claims were in fact filed by the medical providers he identified." *Id.* at 38a.

DISCUSSION

Neither of the questions presented warrants the Court's review in this case. With respect to the first question, the court of appeals' interpretation of the FCA's "original source" provision, 31 U.S.C. 3730(e)(4)(B), deepens an existing conflict between decisions of several other courts of appeals. Congress has effectively resolved that conflict, however, by amending Section 3730(e)(4)(B)'s definition of the term "original source." Because the first question presented concerns the interpretation of a now-superseded statutory provision, it is not of sufficient continuing importance to warrant plenary review by this Court.

With respect to the second question, the court of appeals correctly held that a *qui tam* complaint may be sufficiently particularized to satisfy Federal Rule of Civil Procedure 9(b) even if it does not identify specific false claims that are alleged to have been submitted. On that issue as well, the court of appeals' decision deepens an existing circuit conflict, and this Court's review likely would be warranted in an appropriate case. This case, however, is not a suitable vehicle for resolving the Rule 9(b) question. Because former 31 U.S.C. 3730(e)(4) limited the subject-matter jurisdiction of the federal courts, the Court could not address the Rule 9(b) issue in this case unless it first determined (contrary to petitioner's position) that respondent qualified as an "original source" under pre-PPACA law. As a result, the jurisdictional question (which is not of continuing importance) might prevent the Court from reaching the Rule 9(b) question (which is of continuing importance). Accordingly, the Court should deny the petition for a writ of certiorari.

A. Because Congress Recently Amended The FCA's Definition Of The Term "Original Source," The First Question Presented Is Not Of Sufficient Continuing Importance To Warrant This Court's Review

1. The version of the FCA that governs this case divests courts of jurisdiction over any *qui tam* action "based upon the public disclosure of allegations" of fraud, "unless * * * the person bringing the action is an original source of the information." 31 U.S.C. 3730(e)(4)(A). Section 3730(e)(4)(B) establishes two criteria that a relator must satisfy in order to qualify as an "original source." The relator must have (1) "direct and independent knowledge of the information on which the allegations are based," and he must have (2) "voluntarily provided the information to the Government before filing an action * * * which is based on the information." 31 U.S.C. 3730(e)(4)(B).

In this case, petitioner does not appear to dispute that respondent had "direct and independent knowledge of the information" that formed the basis of his *qui tam* complaint. Petitioner argues, however, that respondent does not satisfy the second prerequisite to "original source" status because he did not provide the information to the government until after the relevant public disclosure had occurred. The courts of appeals are divided over precisely when a relator must provide the government with the information on which his suit is based in order to qualify as an "original source."[3]

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[3] In *Rockwell International Corp.* v. *United States*, 549 U.S. 457 (2007), this Court held that, in order to qualify as an "original source," a relator must have "direct and independent knowledge of the information" that is the basis for the allegations in his complaint. *Id.* at 470-472. The Court did not address, however, when a relator must provide such

In the decision below, the First Circuit joined the Fourth and Eighth Circuits in holding that a relator need only provide his information to the government before filing his *qui tam* action. Pet. App. 16a-30a; see *United States ex rel. Siller* v. *Becton Dickinson & Co.*, 21 F.3d 1339, 1351-1355 (4th Cir.), cert. denied, 513 U.S. 928 (1994); *Minnesota Ass'n of Nurse Anesthetists* v. *Allina Health Sys. Corp.*, 276 F.3d 1032, 1050-1051 (8th Cir.), cert. denied, 537 U.S. 944 (2002). By contrast, the District of Columbia and Sixth Circuits have held that a relator must provide his information to the government prior to the public disclosure of the relevant fraud allegations. See *United States ex rel. Findley* v. *FPC-Boron Employees' Club*, 105 F.3d 675, 690-691 (D.C. Cir.), cert. denied, 522 U.S. 865 (1997); *United States ex rel. McKenzie* v. *BellSouth Telecomms., Inc.*, 123 F.3d 935, 941-943 (6th Cir. 1997), cert. denied, 522 U.S. 1077 (1998). And the Second and Ninth Circuits have adopted an altogether different approach by holding that, regardless of when a relator provides his information to the government, he must be the source of the public disclosure in order to bring his own *qui tam* action. See *United States ex rel. Dick* v. *Long Island Lighting Co.*, 912 F.2d 13, 16 (2d Cir. 1990); *Wang* v. *FMC Corp.*, 975 F.2d 1412, 1418-1419 (9th Cir. 1992).

Before the recent amendments to Section 3730(e)(4)(B), the government repeatedly argued, including in the court of appeals in this case, that the rule adopted by the District of Columbia and the Sixth Circuits best accords with the text, structure, and purpose of that provision. In order to be naturally characterized

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information to the government in order to come within the definition of "original source" contained in 31 U.S.C. 3730(e)(4)(B).

as a "source" of information "provided" to the government, 31 U.S.C. 3730(e)(4)(B), a relator must turn over to the government information that is not already in the public domain or otherwise in the government's possession. See *McKenzie*, 123 F.3d at 942; *Findley*, 105 F.3d at 690-691. Moreover, requiring a relator to provide his information to the government in advance of any public disclosure serves the FCA's purpose of alerting the government to potential fraud. See *McKenzie*, 123 F.3d at 942-943. A relator who gives his information to the government after a public disclosure has already occurred does little or nothing to further that central objective.

2. As amended, Section 3730(e)(4)(B) allows a relator to qualify as an "original source" in either of two ways. First, the relator will qualify if, "prior to a public disclosure," he "voluntarily disclose[s] to the [g]overnment the information on which allegations or transactions in a claim are based." PPACA, Pub. L. No. 111-148, 124 Stat. 901 (to be codified at 31 U.S.C. 3730(e)(4)(B)(i) (Supp. IV 2010)). Second, if the relator "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," then he will qualify as an "original source" if he "voluntarily provide[s] the information to the [g]overnment before filing [a *qui tam*] action." 124 Stat. 902 (to be codified at 31 U.S.C. 3730(e)(4)(B)(ii) (Supp. IV 2010)).

The two-part definition of "original source" set forth in amended Section 3730(e)(4)(B) does not precisely correspond to any circuit's interpretation of the prior provision. In order to qualify as an "original source" under new Section 3730(e)(4)(B)(i), a relator must provide his information to the government prior to the public disclosure of the relevant fraud allegations. That requirement

essentially tracks the construction of the pre-PPACA provision that the District of Columbia and Sixth Circuits had adopted. Even a relator who does not satisfy that requirement, however, can qualify as an "original source" under new Section 3730(e)(4)(B)(ii) if he comes forward with information that materially adds to the publicly disclosed allegations and provides that information to the government before filing suit. That provision establishes a test for "original source" status that had not previously been adopted by any court of appeals.

3. If Section 3730(e)(4) had not been amended, the first question presented in the petition may have warranted resolution by this Court. By amending Section 3730(e)(4), however, Congress clarified the law going forward and thereby obviated the need for this Court's intervention. To be sure, the question presented will have some continuing practical significance because former Section 3730(e)(4) remains applicable to suits that were filed before the PPACA was enacted. See p. 4, *supra*.[4] That sort of continuing effect, however, is a nat-

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[4] This Court has recognized that the PPACA "makes no mention of retroactivity, which would be necessary for its application to pending cases." *Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010). In *Hughes Aircraft Co.* v. *United States ex rel. Schumer*, 520 U.S. 939 (1997), the Court held that FCA amendments enacted in 1986, which expanded the range of permissible *qui tam* actions by replacing the prior "government knowledge" bar on *qui tam* suits with the "public disclosure" bar contained in Section 3730(e)(4), likewise should not be given retroactive effect. See *id.* at 945-951. The Court in *Hughes Aircraft* further explained that, "[b]ecause both the allegedly false claim submission and the disclosure to the Government of information about that submission occurred prior to the effective date of the 1986 amendments, we need not address which of these two events constitutes the relevant conduct for purposes of our retroactivity analysis." *Id.* at 946 n.4. Under

ural and routine consequence of the presumption against statutory retroactivity, and it is not a sufficient reason for this Court to grant plenary review to construe a superseded FCA provision. Accordingly, this Court should deny certiorari on the first question presented.

B. In Light Of The Potential Jurisdictional Barrier To Respondent's Suit, This Case Is Not An Appropriate Vehicle For Addressing The Proper Application Of Federal Rule Of Civil Procedure 9(b) To *Qui Tam* Complaints Under The FCA

1. In this case, the court of appeals held that a relator can "satisfy [Federal Rule of Civil Procedure] Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." Pet. App. 33a (quoting *United States ex rel. Rost* v. *Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)). Applying that standard, the court noted that respondent had named eight medical providers who had allegedly provided false claims. *Id.* at 34a-35a. In addition, respondent had supplied the approximate "dates and amounts of the false claims filed by these providers with the Medicare program." *Id.* at 35a. The court of appeals therefore concluded that respondent had alleged with sufficient particularity "that false claims were in

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Graham County (which indicates that the PPACA does not apply to "pending cases") and *Hughes Aircraft*, it is unclear whether the application of amended Section 3730(e)(4) turns on the date when the alleged false claims were submitted, the date when the public disclosure occurred, or the date when the *qui tam* suit was filed. Under any of those approaches, however, suits like this one, in which the relator's complaint was filed before the PPACA's enactment, will be governed by the prior version of Section 3730(e)(4).

fact filed by the medical providers he identified." *Id.* at 38a.

The court of appeals' decision is correct and consistent with recent decisions of other courts of appeals. Rule 9(b) does not impose an absolute requirement that a relator identify a specific false claim submitted to the government in order to avoid dismissal of his complaint. Although a plaintiff "must state with particularity the circumstances constituting fraud or mistake," Fed. R. Civ. P. 9(b), a *qui tam* complaint may be sufficiently detailed and particularized to satisfy that requirement even though it does not identify specific false claims. See *United States ex rel. Lusby* v. *Rolls-Royce Corp.*, 570 F.3d 849, 854-855 (7th Cir. 2009) (Easterbrook, C.J.); *United States ex rel. Grubbs* v. *Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009). As the Seventh Circuit explained in *Lusby*, it is not "essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit." 570 F.3d at 854. Indeed, even a relator with detailed knowledge of the manner in which a fraudulent scheme was executed may lack access to that type of paperwork. *Ibid.*

2. By contrast, other courts of appeals have issued decisions stating that particular *qui tam* complaints should be dismissed under Rule 9(b) because relators had failed to identify specific false claims for payment submitted to the government. See *United States ex rel. Bledsoe* v. *Community Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) ("We hold that pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)."); see also *United States ex rel. Sikkenga* v. *Regence BlueCross BlueShield*, 472 F.3d 702, 727-728 (10th Cir. 2006) (affirming dismissal of

cause of action that failed "to identify any specific [false] claim"); *United States ex rel. Atkins* v. *McInteer*, 470 F.3d 1350, 1358-1360 (11th Cir. 2006) (same); *United States ex rel. Joshi* v. *St. Luke's Hosp., Inc.*, 441 F.3d 552, 560 (8th Cir.) (requiring the relator to plead "some representative examples" of false claims), cert. denied, 549 U.S. 881 (2006). At least one of those circuits has not consistently adhered to that understanding of Rule 9(b).[5] At a minimum, however, the overall body of appellate precedent creates substantial uncertainty as to whether a *qui tam* complaint that contains detailed allegations giving rise to a reasonable inference that false claims were submitted to the government, but that does not identify specific requests for payment, can be sufficiently particularized to withstand a motion to dismiss.

That uncertainty hinders the ability of *qui tam* relators to perform the role that Congress intended them to play in the detection and remediation of fraud against the United States. *Qui tam* complaints under

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[5] Contrast *Hopper* v. *Solvay Pharms., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009) (holding that a relator must plead a specific false claim to avoid dismissal of his complaint), petition for cert. pending, No. 09-1065 (filed Mar. 4, 2010), with *United States ex rel. Walker* v. *R&F Props. of Lake County, Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005) (permitting a relator to allege detailed information about a fraudulent scheme supporting an inference that the defendant submitted false claims), cert. denied, 549 U.S. 1027 (2006), and *United States ex rel. Clausen* v. *Laboratory Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (stating that a *qui tam* complaint must contain "some indicia of reliability * * * to support the allegation of an actual false claim for payment") (emphasis omitted), cert. denied, 537 U.S. 1105 (2003). Cf. *Bledsoe*, 501 F.3d at 504 n.12 (declining to address whether a complaint must be dismissed "where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that the relator cannot produce such allegations is not attributable to the conduct of the relator").

the FCA are often filed by the defendants' employees and former employees. Such relators may know that their employers are receiving funds from the United States, and they may be privy to detailed information indicating that the employers' actual practices differ markedly from their representations to the federal government. Under the reading of Rule 9(b) that petitioner advocates, however, those relators would be disabled from filing suit under the FCA unless they were also familiar with the minutiae of their employers' billing practices.

Subjecting *qui tam* relators to that requirement is especially unwarranted because it attaches elevated significance to the relator's awareness of facts that in most instances are already known to the government. The government rarely if ever needs a relator's assistance to identify claims for payment that have been submitted to the United States. Rather, relators who make valuable contributions to the government's enforcement efforts typically do so by bringing to light information, outside the four corners of the claims for payment, that shows those claims to be false. Requiring *qui tam* complaints to identify specific false claims would not meaningfully assist the government's enforcement efforts. To the contrary, the likely effect of such a requirement would be to discourage the filing of *qui tam* suits by relators who would otherwise have both the means and the incentive to expose acts of fraud against the United States.

3. For the foregoing reasons, the second question presented in the petition is both unsettled and significant, and in an appropriate case it might well warrant the Court's review. This case, however, is not a suitable vehicle for addressing the application of Rule 9(b) to *qui tam* suits under the FCA. Because the question wheth-

er respondent qualifies as an "original source" under former Section 3730(e)(4)(B) goes to the subject-matter jurisdiction of the federal courts, see *Rockwell Int'l Corp.* v. *United States*, 549 U.S. 457, 467-470 (2007), the Court would be required to decide that issue before considering whether respondent's complaint pleaded fraud with adequate particularity. As explained above, plenary review of the antecedent jurisdictional question, which involves the construction of superseded statutory language, is neither necessary nor appropriate at this time. See pp. 13-14, *supra*. And if the Court were to conclude that respondent is not an "original source" under the now-superseded version of Section 3730(e)(4)(B), it could not resolve the Rule 9(b) issue that has continuing importance in future cases. Accordingly, this Court should deny certiorari on the second question presented.[6]

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[6] The question whether a relator must identify a specific false claim in order to satisfy Rule 9(b) appears to be squarely presented in another case that is currently pending before the Court and that does not appear to contain any potential jurisdictional obstacle. See *United States ex rel. Hopper* v. *Solvay Pharms., Inc.*, No. 09-1065 (filed Mar. 4, 2010). The government is providing copies of this brief to counsel for the parties in *Hopper*.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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IN THE

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ORTHO BIOTECH PRODUCTS, L.P.,
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v.

UNITED STATES EX REL. MARK EUGENE DUXBURY,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF AMICUS CURIAE OF THE AMERICAN HOSPITAL ASSOCIATION IN SUPPORT OF PETITIONER

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BRIEF AMICUS CURIAE OF THE AMERICAN HOSPITAL ASSOCIATION IN SUPPORT OF PETITIONER

STATEMENT OF INTEREST OF AMICI CURIAE[1]

Founded in 1898, the American Hospital Association ("AHA") is the national advocacy organization for hospitals in this country. It

[1] Pursuant to Sup. Ct. R. 37.6, *amicus curiae* notes that no counsel for a party authored this brief in whole or in part, and no counsel or party, other than *amicus curiae* and its members, made a monetary contribution intended to fund the preparation or submission of this brief. Consent letters from the parties have been filed with the Clerk, and the parties were provided the notice required by Sup. Ct. R. 37.2.

represents approximately 5,000 hospitals, health care systems, and other health care organizations, as well as 37,000 individual members. AHA's mission is to promote high quality health care and health services through leadership and assistance to hospitals in meeting the health care needs of their communities. AHA advocates on behalf of its members in legislative, regulatory, and judicial fora as part of its commitment to improving health care policy and health care delivery for the communities that its members serve.

One way in which AHA promotes the interests of its members is by participating as *amicus curiae* in cases with important and far-ranging consequences for its members—including cases arising under the False Claims Act ("FCA"). *See, e.g.*, *Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 129 S. Ct. 2824 (2009); *Allison Engine Co., Inc.* v. *United States ex rel. Sanders*, 128 S. Ct. 2123 (2008); *Rockwell Int'l Corp.* v. *United States*, 549 U.S. 457 (2007); *Vermont Agency of Natural Res.* v. *United States ex rel. Stevens*, 529 U.S. 765 (2000).

This is such a case. The questions presented in this petition are of great importance to AHA's members. The Federal Government funds in full or in part a substantial percentage of the health care services AHA's members provide, including under the Medicare and Medicaid statutes and accompanying regulations—described by this Court as "Byzantine" texts "among the most intricate ever drafted by Congress." *Schweiker* v. *Gray Panthers*, 453 U.S. 34, 43 (1981).

AHA is concerned that the First Circuit's decision, if not reversed, will undermine two critical requirements for FCA actions: that a relator not

trade on allegations of fraud already disclosed to the public (the jurisdictional limitation in the public disclosure bar) and that a relator have specific pre-filing knowledge of some false or fraudulent claims (the Rule 9(b) pleading standard). Both requirements impose important limitations on who can bring an FCA suit and what knowledge of wrongdoing a plaintiff must have before filing suit. The decision below, however, improperly extends the Act's jurisdictional reach to relators who file tag-along law suits *after* public disclosures of allegedly false claims have already brought to light an alleged fraud. It also improperly permits relators to pursue claims under the *False Claims* Act notwithstanding a lack of specific knowledge of *any false claims*.

These twin holdings—and the circuit splits they exacerbate—will only encourage the filing of dubious *qui tam* suits based on publicly disclosed allegations of fraud or on mere hunch and speculation, given that the FCA has become the clear tool of choice to extract large damage awards and settlements for alleged missteps in Government-funded health care programs. The AHA anticipates that the First Circuit's decision will create additional improper incentives for the filing of questionable (at best) *qui tam* lawsuits. *Qui tam* lawsuits are expensive to investigate and defend, especially when brought by a growing cottage industry that is enticed by the financial prospects of FCA settlements. The *qui tam* provision should not be a vehicle for plaintiffs who hope that the discovery process may unearth some impropriety in a defendant's compliance with the "morass of bureaucratic complexity" of the federal health care programs. *Herweg* v. *Ray*, 455 U.S. 265, 279 (1982) (Burger, C.J., dissenting). The First

Circuit's decision furthers abuse of the FCA in just that way.

FCA *qui tam* lawsuits have proliferated over the past two decades. In 1987, there were 30 such cases filed; in 2009, *433* were filed—and the majority involved health care entities. *See* United States Dep't of Justice, Civil Division, *Fraud Statistics—Overview, Oct. 1, 1987-Sept. 30, 2009, available at* http://www.justice.gov/civil/frauds/fcastats.html. In fact, over 61% of the *qui tam* actions filed from 2000-2009 involved allegations of health care fraud. *Id.*; *see also* GAO, Letter to Hon. F. James Sensenbrenner, Jr., Hon. Chris Cannon, and Hon. Charles E. Grassley, *Information on False Claims Act Litigation* 28 (Jan. 31, 2006) (noting prevalence of *qui tam* cases involving allegations of health care fraud), *available at* http://www.gao.gov/new.items/d06320r.pdf. The public disclosure and Rule 9(b) limitations on FCA actions are important to hospitals and health care organizations, which are prime targets for abusive *qui tam* lawsuits for two reasons: they are subject to numerous extraordinarily complicated and often ambiguous statutes and regulations; and they submit a substantial number of claims (and receive a substantial amount of federal funds) for providing care to individuals participating in federal health programs.

Even as the number of *qui tam* suits has grown tenfold during the last decade, the United States Government—after investigating the allegations—continues to decline to pursue *more than two-thirds* of those lawsuits. That leaves those actions to be prosecuted by relators alone, motivated largely by

the statute's "essentially punitive" damages[2] and contingent bounty provision and not constrained by the institutional wisdom and discretion that tempers the zeal of federal prosecutors. *Cf. Hughes Aircraft Co.* v. *United States ex rel. Schumer*, 520 U.S. 939, 949 (1997) ("*Qui tam* relators are * * * less likely than is the Government to forgo an action arguably based on a mere technical noncompliance with reporting requirements that involved no harm to the public fisc.").

AHA accordingly has a strong interest in the proper enforcement of the FCA's jurisdictional limitations and Rule 9(b)'s particularized pleading standard that accompanies allegations of FCA violations, like any fraud allegation. These boundaries of FCA jurisprudence are necessary aids to discerning between cases prosecuted by legitimate relators with credible knowledge of undisclosed fraud and "parasitic" FCA cases. *See False Claims Act Implementation: Hearing Before Subcomm. on Admin. Law and Gov't Relations of House Comm. on Judiciary*, 101st Cong., 2d Sess. 3 (1990) (1986 amendments to False Claims Act "sought to resolve the tension between * * * encouraging people to come forward with information and * * * preventing parasitic lawsuits") (statement of Sen. Grassley).

The costs of defending FCA suits are immense and increase the already substantial costs of doing

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[2] *Vermont Agency of Natural Res.*, 529 U.S. at 784. The FCA imposes treble damages and penalties of $5,500-$11,000 for every "false claim." 31 U.S.C. § 3729(a); 64 Fed. Reg. 47099, 47104 (Aug. 30, 1999), *codified at* 28 C.F.R. § 85.3(a)(9). Relators are entitled to 15-30 percent of the proceeds of an action or settlement of a claim. 31 U.S.C. § 3730(d)(1)-(2).

business for AHA's members, which in turn increases pressure on health care costs for all Americans and diverts needed resources from providing patient care. AHA thus supports Petitioner's request that this Court grant its petition for writ of certiorari.

SUMMARY OF ARGUMENT

The issues raised in this case involve the original source exception to the FCA's public disclosure bar and application of Rule 9(b)'s heightened pleading standard in the FCA context. The FCA's public disclosure bar, as the Court recognized three terms ago, is a "jurisdiction removing provision." *Rockwell Int'l Corp.*, 549 U.S. at 468. Under this bar, a court lacks jurisdiction over a *qui tam* claim that is based on publicly disclosed allegations *unless* the relator is an "original source" of the information on which the allegations are based. 31 U.S.C. § 3730(e)(4). How and when the bar—and its exception—applies is a frequently litigated issue. Just as frequently litigated is whether a *qui tam* complaint satisfies the heightened pleading requirement of Rule 9(b), which requires fraud plaintiffs (including relators) to plead "with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).[3]

The First Circuit's decision substantially waters down both of these fundamental constraints on a relator's pursuit of a *qui tam* claim, and the bounty

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[3] By our count, there have been over 100 lower court decisions discussing application of this jurisdictional bar and its exception just since the Court's *Rockwell* decision issued a few Terms ago. During this same time frame, there have been over 130 lower court decisions discussing the application of Rule 9(b) to FCA claims.

that accompanies it. Instead of interpreting the original source exception to further the statutory goal of ensuring that only true whistleblowers are deputized to pursue FCA actions on behalf of the United States—as the Second, Sixth, Ninth, and D.C. Circuits have done [4]—the First Circuit held that a relator can qualify as an original source even if his complaint merely rehashes allegations previously raised in other litigation, and even though he did not inform the Government of the alleged fraud before it was publicly disclosed to the Government through other channels.

Besides conflicting with the interpretation of four sister circuits, the First Circuit's original source holding is contrary to the position of the United States—on whose behalf a relator like Duxbury purports to be litigating. Just last Term, the Court reiterated that the United States is "a 'real party in interest' in a case brought under the FCA." *United States ex rel. Eisenstein* v. *City of New York*, 129 S. Ct. 2230, 2232 (2009). And as that "real party in interest" explained in its *amicus* submission below: "Individuals who provide their information to the Government *after* that information has been publicly

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[4] *See United States ex rel. Dick* v. *Long Island Lighting Co.*, 912 F.2d 13 (2d Cir. 1990); *United States ex rel. McKenzie* v. *Bellsouth Telecomm., Inc.*, 123 F.3d 935 (6th Cir. 1997); *United States ex rel. Wang* v. *FMC Corp.*, 975 F.2d 1412 (9th Cir. 1992); *United States ex rel. Findley* v. *FPC-Boron Employees' Club*, 105 F.3d 675 (D.C. Cir. 1997). *But see United States ex rel. Siller* v. *Becton Dickinson & Co.*, 21 F.3d 1339, 1355 (4th Cir. 1994) (adopting same holding as First Circuit); *Minnesota Ass'n of Nurse Anesthetists* v. *Allina Health System Corp.*, 276 F.3d 1032, 1051 (8th Cir. 2002) (same).

disclosed do little to assist the Government in identifying fraud, and *qui tam* cases filed by such individuals are largely unnecessary." U.S. Amicus Brief in *United States ex rel. Duxbury* v. *Ortho Biotech Products, LP*, 1st Cir. Case No. 08-1409, at 23 (emphasis in original). The First Circuit thus has adopted a minority interpretation that undermines the FCA's purposes and is contrary to the position of the real party in interest in whose name FCA claims are prosecuted.

The First Circuit's creation of what it called a "more flexible" Rule 9(b) pleading standard for FCA cases—apparently applicable when a relator cannot plead the specifics of any false claim that the defendant allegedly caused a third-party to submit—also merits review. Pet. App. 35a. The FCA is a fraud statute. Fraud allegations are not to be lightly brought or allowed. This Court has not had the occasion to analyze the pleading standard for fraud, and in particular, whether a party can meet that standard where it lacks any detailed allegations as to a core element of its claim. The FCA, to be clear, does not create liability for violations of federal law *independent* of a false claim. It creates liability for *false claims*—both for those who knowingly submit those claims and those who knowingly cause them to be submitted. But the First Circuit exempted relators like Duxbury from Rule 9(b)'s requirement to plead the circumstances of fraud—which in the FCA context includes the false or fraudulent claim—with particularity.

The standard adopted by the court below was that a relator need only allege facts from which a court can infer more than a possibility of fraud. Pet. App.

33a, 38a. This holding conflicts not only with the view of other circuits that recognize the false claim itself is the "*sine qua non*" of a FCA action,[5] but also demotes the Rule 9(b) particularized pleading requirement to nothing higher than the standard pleading requirement applicable under Rule 8(a). *See Ashcroft* v. *Iqbal*, 129 S. Ct. 1937 (2009); *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544 (2007). To meet Rule 8(a)'s standard pleading burden, a claim must be facially plausible, i.e., the plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" and must provide "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S. Ct. at 1949. The Rule 9(b) standard, which applies to "subjects understood to raise a high risk of abusive litigation," *Twombly*, 550 U.S. at 569 n.14, is something higher—but to date, this Court has not addressed what must be pleaded to satisfy that higher standard.

The petition's first question presented—on the original source exception—addresses an issue left unresolved in *Rockwell*. The second question presented—on the rigor of the Rule 9(b) pleading standard—logically relates to, and furthers, the

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[5] *See, e.g.*, *Hopper* v. *Solvay Pharms., Inc.*, -- F.3d --, 2009 WL 4429519, at *8 (11th Cir. Dec. 4, 2009) ("We have repeatedly held that the submission of a false claim is the '*sine qua non* of a False Claims Act violation.' ") (quoting *United States ex rel. Clausen* v. *Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *United States ex rel. Marlar* v. *BWXT Y-12, LLC*, 525 F.3d 439, 447 (6th Cir. 2008) (reiterating view that a "fraudulent claim is 'the *sine qua non* of a False Claims Act violation' ") (citations omitted).

Court's recent pleading standard decisions. The varying positions taken by the circuit courts on both issues in the questions presented create an unacceptable level of uncertainty. This uncertainty in turn increases the substantial incentives for plaintiffs to file *qui tam* actions based on already public allegations or speculative guesswork, and to forum-shop in the process. These questions are important and recurring and warrant certiorari review.

ARGUMENT

I. The Court Should Grant Certiorari To Resolve The Circuit Split As To When The Original-Source Exception Provides Federal Court Jurisdiction Over An FCA Claim.

1. As the petition explains, the circuits are split on when a relator must provide information on an alleged fraud to the Government to qualify as an original source and thereby invoke court federal jurisdiction. Pet. 16-21.[6] Whether the federal courts

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[6] In addition to the seven-circuit split discussed in the petition, district courts in circuits that have not directly addressed this issue are also split. *Compare United States ex rel. Merena* v. *Smithkline Beecham Corp.*, 114 F. Supp. 2d 352, 361 (E.D. Pa. 2000) (disagreeing "with the government's argument that a relator must 'come forward with his "voluntary disclosure to the government" before the public disclosure of the allegations and transactions involved in his complaint to qualify as an "original source" ' ") *with United States ex rel. Eaton* v. *Kansas Healthcare Investors, II, LP*, 22 F. Supp. 2d 1230, 1236 (D. Kan. 1998) (recognizing that the Sixth and D.C. Circuits interpret the original source exception as met only when a relator informs the Government of the alleged fraud prior

have jurisdiction over a claim should not turn on flukes of geography. That is especially so in this context, given a potential relator's option to forum-shop for the best circuit's law in which to bring a claim under the FCA's broad venue provision. *See* 31 U.S.C. § 3732(a) (FCA action "may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred.").[7]

Here, in fact, the (unidentified) false claims that Petitioner allegedly "caused" to be submitted were submitted in Washington State, which lies in the Ninth Circuit. *See* Pet. App. 34a. But by bringing suit in Massachusetts instead, Duxbury was able to circumvent Ninth Circuit precedent on the original source exception to the public disclosure bar—precedent under which his claims would have clearly been jurisdictionally barred. Under the Ninth Circuit's standard, *qui tam* jurisdiction "extend[s]

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to public disclosures and holding that "[t]he court believes the Tenth Circuit would likely adopt this requirement").

[7] One commentator specifically advocates for such forum-shopping based on the varying interpretations of the public disclosure bar and original source exception. Carolyn V. Metnick, *The Jurisdictional Bar Provision: Who is an Appropriate Relator?*, 17 Annals Health L. 101, 103 (Winter 2008) (advocating that "where a large, national healthcare entity is involved, multiple courts may have jurisdiction and venue to hear a given case," and a relator "should determine which court will view his case most favorably" and specifically should consider each court's "analysis of the jurisdictional bar provision") (emphasis added); *see also id.* at 104, 132-133.

only to those who * * * played a part in publicly disclosing the allegations and information on which their suits" are based. *United States ex rel. Wang*, 975 F.2d at 1418. According to the Ninth Circuit, the FCA's *qui tam* provisions aim "to encourage insiders privy to a fraud on the government to blow the whistle on the crime" while avoiding rewards paid from the public fisc for a "second toot" on that whistle. *Id.* at 1419; *see also United States* v. *Johnson Controls, Inc.*, 457 F.3d 1009, 1018 (9th Cir. 2006) (noting the circuit conflict and explaining that "[u]nder our interpretation of that [original source] exception, then, relators *must* provide a useful information-providing role or they cannot file suit"). Federal court jurisdiction should not emerge from such blatant forum-shopping.

2. Granting this petition will resolve the circuit split and close a hole left open in the Court's *Rockwell* decision. As the United States explained in its amicus brief to the First Circuit below:

> In *Rockwell*, the Supreme Court clarified what qualifies as "direct and independent knowledge" sufficient to qualify as an original source, *Rockwell*, 127 S. Ct. 1407-10, but the courts of appeals remain somewhat divided on the question of *when* a relator must provide his information to the Government in order to qualify as an original source.

U.S. Amicus Brief at 21 (discussing the varying interpretations offered by the Second, Fourth, Sixth, Ninth, and D.C. Circuits on this issue).[8] The United

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[8] *See also* Metnick, *supra*, 17 Annals Health L. at 132-133 ("Although the United States Supreme Court has

States asserted that "the most natural construction" of the provision "is that it requires a relator to provide information to the Government that is not already in the public domain." *Id.* at 22. A relator should qualify as an original source and thus be granted jurisdiction to pursue claims for the "large bounties" available to FCA relators only where the relator provides valuable non-publicly disclosed information to the Government. *Id.* at 22-23. Given that the Government itself views Duxbury's *qui tam* lawsuit as an attempt to improperly claim monies that, if recovered, should flow to the public fisc and its health care trust funds, the First Circuit's decision to find jurisdiction for Duxbury's "second toot" is at best questionable.

3. The First Circuit's opinion—unlike the Second, Sixth, Ninth, and D.C. Circuits—runs afoul of at least three principles of statutory construction that demonstrate the error of its decision. *First*, the First Circuit's interpretation is contrary to the purpose of the public disclosure bar—removing jurisdiction over claims based on public disclosures unless the claim does not amount to a tag-along parasitic lawsuit. A statute should not be construed in a way that "frustrate[s] Congress' manifest purpose." *United States* v. *Hayes*, 129 S. Ct. 1079, 1087 (2009). *See*,

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provided [in *Rockwell*] some much needed clarification on the issue of the 'direct and independent knowledge' needed to satisfy the original source exception, much of the language in the jurisdictional bar provision remains unclear. Whether a relator will proceed beyond the jurisdictional bar depends significantly on the circuit in which he files the *qui tam* suit. * * * Despite some clarification, the circuits remain split over the meaning of original source.").

e.g., *In re Natural Gas Royalties Qui Tam Litig.*, 566 F.3d 956, 961 (10th Cir. 2009) (the public disclosure bar "function[s] to weed out parasitic claims") (citing *Grynberg* v. *Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004) ("Once the government is put on notice of its potential fraud claim, the purpose behind allowing *qui tam* litigation is satisfied.")).

Second, the First Circuit's interpretation leads to absurd, and inequitable, results. *See, e.g.*, *Rowland* v. *California Men's Colony, Unit II Men's Advisory Council*, 506 U.S. 194, 200-201 (1993) (noting "the common mandate of statutory construction to avoid absurd results"); *United States* v. *Brown*, 333 U.S. 18, 26 (1948) (explaining that statutes should not be interpreted to "lead to bizarre results" that "frustrate[ ]" congressional purpose). An example of the absurdity that flows from the decision below: If the U.S. Government Accountability Office (GAO) released a public report disclosing fraudulent claims submitted by a government contractor in Iraq, a savvy relator who read the GAO report *and* had some direct and independent knowledge of those claims could then file a *qui tam* suit and qualify as an original source—thereby claiming a sizeable portion of any recovery returned to the U.S. Treasury—just by giving the Government information duplicative to that disclosed in the GAO's report the day before filing suit.[9]

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[9] *See, e.g.*, *United States ex rel. McKenzie*, 123 F.3d at 942 (explaining that the purpose of the FCA is to reward "true whistleblowers" and that "it is difficult to understand how one can be a 'true whistleblower' unless she is responsible for alerting the government to the

And *finally*, the First Circuit's interpretation ignores that, as courts of limited jurisdiction, "[t]he public disclosure bar must be strictly construed, with all doubts resolved against jurisdiction." U.S. Amicus Brief in *United States ex rel. Kennard* v. *Comstock Resources*, 10th Cir. Case No. 03-8012 (filed Apr. 29, 2003) (citations omitted), *available at* 2003 WL 24167056. *Accord United States ex rel. Holmes* v. *Consumer Ins. Group*, 318 F.3d 1199, 1215 (10th Cir. 2003) ("When considering federal subject-matter jurisdiction, we must presume that jurisdiction is lacking, require the party asserting jurisdiction to prove that it exists, and resolve all doubts against jurisdiction."); *United States ex rel. Coleman* v. *Indiana*, 2000 WL 1357791, at *9 (S.D. Ind. 2000) (holding that because "[a] federal court is a court of limited jurisdiction," then "[a]ny doubt as to the court's jurisdiction should be resolved against jurisdiction") (citing, *inter alia*, *Kokkonen* v. *Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994)); *Wercinski* v. *Int'l Bus. Mach. Corp.* 982 F. Supp. 449, 453 (S.D. Tex. 1997) (same, also in FCA context).

This burgeoning circuit conflict should be resolved now. Permitting a relator like Duxbury to bring a FCA claim that restates information already in the public domain contradicts Congress's goal of limiting jurisdiction to *qui tam* lawsuits that bring new fraud to light—i.e., suits by true whistleblowers. And it undermines the goal of preventing windfall recoveries by savvy relators with direct and independent knowledge of allegations that are

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alleged fraud before such information is in the public domain").

already known to the Government because they were publicly disclosed by someone else.

II. The Court Should Grant Certiorari To Restore The Strict Rule 9(b) Particularity Pleading Requirement To All FCA Cases.

1. The FCA is an anti-fraud statute. A *qui tam* complaint therefore must satisfy Rule 9(b)'s pleading requirements. And unlike pure notice pleading, Rule 9(b) requires that "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "The reference to 'circumstances' in the rule is to matters such as *the time, place, and contents of the false representations* or omissions, *as well as the identity of the person making the misrepresentation* or failing to make a complete disclosure and what that defendant obtained thereby." Charles A. Wright & Arthur R. Miller, 5A *Fed. Prac. & Proc. Civ.* § 1297 (3d ed. 2004) (emphases added). In the FCA context, as the name implies, it is the *claim* for payment itself that is false or fraudulent; liability thus hinges on the falsity or fraudulent nature of a *claim*—not on details of the broader underlying scheme alone.

The First Circuit's Rule 9(b) ruling, however, created a "more flexible" pleading standard that exempts FCA relators like Duxbury from having to plead any particular details of any allegedly false claim. Relators need only plead allegations that "'strengthen the inference of fraud beyond possibility'" without necessarily providing details as to the claims. Pet. App. 33a. In so ruling, the court of appeals diluted the stringent Rule 9(b) pleading standard to nothing more than the Rule 8(a) notice

pleading standard set out by this Court in *Twombly* and *Iqbal*. The First Circuit's "beyond possibility" standard is certainly no higher—and may even be *lower*—than the "more than a sheer possibility" and "facially plausible" standard articulated in *Twombly* and *Iqbal*.

The conflict with this Court's precedent alone warrants review. Pet. 24-25. While this Court has addressed the Rule 8 pleading standard repeatedly and has addressed heightened pleading standards in other contexts, *see Swierkiewicz* v. *Sorema NA*, 534 U.S. 506 (2002) (considering propriety of heightened pleading standard applied by Courts of Appeals in employment discrimination cases); *Leatherman* v. *Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163 (1993) (considering propriety of heightened pleading standard applied by Courts of Appeals in municipal liability context), the Court has not to date directly tackled the Rule 9(b) pleading-with-particularity standard. This case presents a strong vehicle for doing so, as the argument is fully developed and the time is ripe for addressing the issue

2. When faced with similar arguments for softening the Rule 9(b) standard for *qui tam* relators, other circuits have refused the invitation. As the Fifth Circuit has explained, "[a] special relaxing of Rule 9(b) is a *qui tam* plaintiff's ticket to the discovery process that the statute itself does not contemplate." *United States ex rel. Russell* v. *Epic Healthcare Mgmt. Group*, 193 F.3d 304, 309 (5th Cir. 1999); *see also Wood ex rel. United States* v. *Applied Research Assocs., Inc.*, 328 F. App'x 744, 747, 2009 WL 2143829, at *2 (2d Cir. July 16, 2009) (" 'One of

the [further] purposes of Rule 9(b) is to discourage the filing of complaints as a pretext for discovery of unknown wrongs. [A relator's] contention, that discovery will unearth information tending to prove his contention of fraud, is precisely what Rule 9(b) attempts to discourage.' ") (alterations in original, citation omitted)); *United States ex rel. Sikkenga* v. *Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 728 (10th Cir. 2006) (affirming dismissal of *qui tam* complaint because "Rule 9(b) does not excuse the general and speculative nature of [relator's] allegations").

Because a relator brings a FCA case not for his own alleged injury, but for that of the United States, 31 U.S.C. § 3730, Rule 9(b)'s strict pleading standard ensures that relators both deserve that unique station and are equipped to carry out that weighty charge. Among the numerous purposes Rule 9(b) serves in the FCA context are protecting defendants from "fishing expeditions and strike suits," *United States ex rel. Bledsoe* v. *Community Health Sys. Inc.*, 501 F.3d 493, 510 (6th Cir. 2007), "ensur[ing] that the relator's strong financial incentive to bring an FCA claim—the possibility of recovering between fifteen and thirty percent of a treble damages award—does not precipitate the filing of frivolous suits," *United States ex rel. Atkins* v. *McInteer*, 470 F.3d 1350, 1360 (11th Cir. 2006), and shielding defendants from " 'spurious charges of immoral and fraudulent behavior.' " *Sanderson* v. *HCA–The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006) (citations omitted).[10]

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[10] *Accord United States ex rel. Fowler* v. *Caremark RX, LLC*, 496 F.3d 730, 740 (7th Cir. 2007) (" 'Greater

Rule 9(b)'s pleading standard helps courts discern between "whistle-blowing insiders with genuinely valuable information" and "opportunistic plaintiffs who have no significant information to contribute on their own." *United States ex rel. Findley*, 105 F.3d at 680 (quotation omitted); *see also United States ex rel. Clausen*, 290 F.3d at 1313 n.24 (permitting a plaintiff "to learn the complaint's bare essentials through discovery * * * may needlessly harm a defendant's goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, [contains] baseless allegations used to extract settlements"). Rule 9(b) furthers the FCA's intent of encouraging those with actual knowledge of false claims to come forward, without creating windfalls for individuals with secondhand conjecture or water cooler gossip about wrongdoing. *United States ex rel. Joshi* v. *St. Luke's Hosp., Inc.*, 441 F.3d 552, 558 (8th Cir. 2006).

3. The First Circuit failed to recognize that strict application of Rule 9(b) disadvantages only those

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precomplaint investigation is warranted in fraud cases because public charges of fraud can do great harm to the reputation of a business firm or other enterprise (or individual))." ") (citation omitted); *Bly-Magee* v. *California*, 236 F.3d 1014, 1018 (9th Cir. 2001) (Strict application of Rule 9(b) in FCA context "serves not only to give notice to defendants of the specific fraudulent conduct against which they must defend, but also 'to deter the filing of complaints as a pretext for the discovery of unknown wrongs, to protect [defendants] from the harm that comes from being subject to fraud charges, and to prohibit plaintiffs from unilaterally imposing upon the court, the parties and society enormous social and economic costs absent some factual basis.' ") (citation omitted).

individuals unequipped to press a *qui tam* suit. When a "complaint does little more than hazard a guess that unknown third parties submitted false claims for Medicaid reimbursement," a *qui tam* relator has not met the applicable pleading burden to pursue such fraud claims. *Hopper*, -- F.3d --, 2009 WL 4429519, at *6. There should be no question that "insiders privy to a fraud on the government should have adequate knowledge of the wrongdoing at issue, [and] * * * should be able to comply with Rule 9(b)." *Bly-Magee*, 236 F.3d at 1019.

All *qui tam* relators must meet Rule 9(b). The FCA is designed to reward those with knowledge of fraud with the right to litigate wearing the mantle of the United States. That mantle is not intended for those who would proceed on mere hunches or speculation. The Court should grant certiorari to restore the strict Rule 9(b) particularity pleading requirement to all FCA cases.

III. The Issues Raised By The Petition Are Important To The Health Care Industry And Recur With Frequency In False Claims Act Litigation.

In the last decade, the health care industry has become the primary target of *qui tam* lawsuits under the FCA. *See, e.g.*, United States Dep't of Justice, Civil Division, *Fraud Statistics—Overview, Oct. 1, 1987-Sept. 30, 2009*, *supra*; *FCA Settlements, Judgments in Fiscal 2009 Included $1.6 Billion From Health Care Fraud*, 13 BNA's Health Care Fraud Report 916 (Dec. 2, 2009) ("Of the $2.4 billion in False Claims Act settlements and judgments in fiscal year 2009, health care fraud recoveries accounted for two-thirds, or $1.6 billion[.]"). As of last month,

there were about 985 health care fraud FCA cases pending under investigation by the Department of Justice. *Id.* And the number of FCA cases filed against health care entities is expected to continue to grow. *See, e.g., FCA Changes Likely to Generate More Cases Involving Overpayments, Attorney Panel Says*, 13 BNA Health Care Fraud Reporter 625 (Aug. 12, 2009) ("Amendments to the federal False Claims Act made earlier this year are expected to fuel a growth in whistleblower-generated health care cases.").

The surge in FCA litigation against participants in federal health care programs is of particular concern to health care providers, including AHA's members, given the magnitude of liability that attaches to violations of the FCA and the resulting pressure to settle rather than defend against such allegations. *Vermont Agency of Natural Res.*, 529 U.S. at 784-785 (FCA damages "are essentially punitive in nature"). The relator's bar has shown relentless creativity in crafting new and ever expanding theories of FCA liability and in stretching the *qui tam* provisions to enable private enforcement of the myriad statutory and regulatory regimes that govern health care—through the guise of the FCA's essentially punitive regime.

Relators have attempted to shoehorn the FCA into a mechanism for private citizens to bring suit—as deputized federal prosecutors not bound by prosecutorial discretion—for alleged *criminal* violations of the Anti-kickback Statute, 42 U.S.C. § 1320a-7b, and the Stark Law, 42 U.S.C. § 1395nn. Relators also rely on the FCA to attempt to privately enforce the Food, Drug, and Cosmetic Act of 1938 and its prohibitions against the promotion of off-label

uses of FDA approved drugs. Other theories underlying FCA suits range from false express certifications of compliance to false implied certifications of compliance to medically unnecessary treatments to overpayments (also known as "reverse false claims").

No matter the theory of FCA liability alleged in a given case, before licensing a relator to litigate reputationally harmful allegations in the name of the United States, it is critical to ensure that the court has jurisdiction and the relator has satisfied Rule 9(b)'s particularized pleading standard. These two issues apply with force across the gamut of FCA claims that come before the lower courts. The lucrative nature of FCA actions provides an incentive for plaintiffs to stretch whether they have a jurisdictionally valid claim and to fudge whether they have the necessary quantum of information (rather than just a hunch, guesswork, or speculation) about any false or fraudulent claims to subject a defendant to expensive litigation. That fact increases the importance of rigorous enforcement of the jurisdictional and pleading standards that apply to FCA actions. More than two-thirds of cases are pursued by relators alone because the Department of Justice, after investigation, has declined to pursue the allegations. For defendants, however, the costs of *qui tam* litigation only increase after the Government bows out.

The Court should grant certiorari to resolve the circuit splits on these two critical threshold issues. The Court should embrace a clear, consistent, and meaningful "original source" rule and should construe Rule 9(b) with sufficient rigor to ensure that illegitimate *qui tam* strike suits are properly

dismissed at the outset. Resolving the circuit splits on these fundamentals of FCA litigation will help guarantee that only true whistleblowers who provide useful, timely information to the Government about false claims can demand a bounty from any recovery. That standard will benefit the Government, the courts, and defendants alike.

CONCLUSION

For the foregoing reasons, and those in the petition, the petition for writ of certiorari should be granted.

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IN THE

Supreme Court of the United States

ORTHO BIOTECH PRODUCTS, L.P.,
Petitioner,

v.

UNITED STATES EX REL.
MARK EUGENE DUXBURY,
Respondent.

On Petition for Writ of Certiorari To the United States Court of Appeals For the First Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Amicus curiae addresses the following issue only:

Whether, in a *qui tam* suit filed under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, a relator alleging that the defendant induced a third party to submit false or fraudulent claims, can satisfy Rule 9(b) of the Federal Rules of Civil Procedure without identifying a single false or fraudulent claim, but merely by alleging facts sufficient "to strengthen the inference of fraud beyond possibility."

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation is a public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to promoting limited and accountable government, supporting the free enterprise system, and opposing abusive enforcement actions and civil litigation by the government and private litigants.

To that end, WLF has appeared before this Court and other federal courts in numerous cases raising significant issues regarding the civil False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.* *See, e.g., Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, No. 08-304 (U.S., dec. pending); *Allison Engine Co. v. United States ex rel. Sanders*, 128 U.S. 2123 (2008); *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007); *Hopper v. Solvay Pharmaceuticals, Inc.*, ___ F.3d ___, 2009 U.S. App. LEXIS 26381 (11th Cir., Dec. 4, 2009); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11 (D. Mass. 2008).

WLF is concerned that over the last two decades,

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for WLF provided counsel for Respondent with notice of its intent to file this brief. All parties have consented to the filing of this brief. Letters of consent have been lodged with the Court.

excessive FCA activity has spawned abusive punitive litigation against businesses, both large and small, to the detriment of those businesses, their employees, their shareholders, and the public at large. Respondent's complaint focuses on his allegations that Petitioner Ortho Biotech Products, L.P. improperly promoted sales of its products. But the issue in this case is whether Petitioner violated the FCA, not whether it improperly promoted its products. The complaint cannot state a cause of action under the FCA given its failure to allege with particularity even a single false claim submitted to the federal government for payment. WLF is concerned that if complaints of this sort are deemed sufficient to survive motions to dismiss, the business community will be forced: (1) to settle even insubstantial FCA claims in order to avoid the prohibitive costs of pre-trial discovery; and (2) to refrain from speaking truthfully to doctors and their patients for fear that the plaintiffs' bar will allege that the speech induced violations of the FCA.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing its brief due solely to its interest in enforcing reasonable restraints on FCA litigation. WLF agrees with Petitioner that review is warranted on the first question presented: whether Respondent should qualify as an "original source" despite his failure to provide relevant information to the government until after that information was publicly disclosed. However, this brief addresses only the second question presented: whether the complaint was adequate under Fed.R.Civ.P. 9(b).

STATEMENT OF THE CASE

The FCA's *qui tam* provisions encourage private individuals with knowledge of fraud perpetrated against the United States Treasury to come forward and sue on behalf of the United States. To encourage whistleblowers (known as *qui tam* relators) to come forward and expose such fraud, the federal government pays a bounty of up to 30% of all recoveries. In other words, the FCA's *qui tam* provisions essentially allow the government to "purchase" from private individuals the information they may have about fraud on the United States Treasury. *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 309 (5th Cir. 1999).

The potential bounties available under the FCA's *qui tam* provisions make this mechanism susceptible to abuse by opportunistic bounty hunters masquerading as true whistleblowers. One of the most effective checks on such parasitic lawsuits is Fed.R.Civ.P. 9(b), which provides that any complaint alleging fraud or mistake (as all FCA complaints must do) "must state with particularity the circumstances constituting fraud or mistake." An FCA complaint that fails to comply with Rule 9(b)'s "particularity" requirement is subject to dismissal under Fed.R.Civ.P. 12(b)(6). A central issue in this petition concerns what an FCA plaintiff must plead to meet the "particularity" requirement.

Respondent Mark Duxbury was employed by Petitioner Ortho Biotech Products, L.P. ("OBP") from 1992 to 1998 in a sales capacity. Duxbury's amended complaint (filed in 2006) did not allege that OBP itself

submitted any false claims to the federal government. Rather, he alleged that OBP promoted sales of one of its oncology drugs, Procrit, in a manner that encouraged others to submit false claims to the federal government under the Medicare program.

Duxbury's allegations regarding this improper encouragement fell generally into two categories. First, Duxbury alleged that OBP violated the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, by promoting the use of Procrit for "off-label" uses (*i.e.*, uses for which the Food and Drug Administration (FDA) has not granted marketing authority). Duxbury conceded that the FDCA does not interfere with the authority of doctors and other practitioners to prescribe an FDA-approved drug for any use they deem medically appropriate, even uses that have not been explicitly approved by FDA. Duxbury nonetheless alleged that at least some Procrit off-label prescriptions written during 1992-1998 were not properly reimbursable under Medicare and that practitioners falsely sought (and obtained) Medicare reimbursement for those prescriptions. Duxbury alleged that various of OBP's promotional activities caused practitioners to submit these false claims and/or to get the claims paid, and that OBP should be held civilly liable under 31 U.S.C. § 3729(a)(1) & (2).

Second, Duxbury alleged that OBP paid "kickbacks" to health care practitioners for the purpose of inducing them to prescribe Procrit.[2] These kickbacks

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[2] The federal anti-kickback statute makes it a serious felony to solicit or receive:

allegedly took the form of "free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria." Pet. App. 49a (citing Am. Compl. ¶ 228).

Duxbury alleged that there were several reasons why these alleged kickbacks violated the FCA. First, the reimbursements paid by Medicare for Procrit were based on the drug's Average Wholesale Price (AWP). Duxbury alleged that the AWP for Procrit was calculated without taking into account the alleged secret kickbacks paid by OBP. Duxbury alleged that information provided by OBP (including its failure to disclose the kickbacks) caused Procrit's AWP to be inflated and thereby caused Medicare to pay inflated reimbursements to health care practitioners. Second, Duxbury alleged that health care practitioners could only have obtained reimbursement for Procrit purchases by falsely certifying to federal officials that they had not received kickbacks. Third, health care practitioners allegedly violated the FCA (at OBP's encouragement) by wrongfully seeking "reimbursement" for the free samples they were given by OBP.

> any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program . . .

42 U.S.C. § 1320a-7b(b)(1). Subsection (b)(2) makes it a felony to *pay* a kickback under similar circumstances.

In January 2008, the district court dismissed all of Duxbury's FCA claims under Fed.R.Civ.P. 12(b). Pet. App. 44a-78a. It dismissed the off-label marketing claims under the first-to-file rule of 31 U.S.C. § 3730(b)(5). The court held that Duxbury's claims were barred because another *qui tam* relator had filed a substantially similar FCA claim before Duxbury filed his first amended complaint. *Id.* at 63a-72a. The court dismissed the kickback-related claims under Rule 9(b), finding that Duxbury had failed to state those claims with sufficient particularity. *Id.* at 72a-77a. It faulted the complaint for failing to identify any specific false claim with particularity (*e.g.*, the date and amount of the claim and the identity of those involved with the billing). *Id.*

The First Circuit affirmed the dismissal of Duxbury's off-label claims but reversed and remanded with respect to the kickback-related claims. *Id.* at 1a-43a. The appeals court conceded that the adequacy of the kickback-related claims was a "close call," in light of Duxbury's failure to "identify any specific claims" submitted by a health care practitioner to Medicare officials. *Id.* at 35a-36a. But the appeals court held that the district court should have applied a "more flexible standard" in determining whether Rule 9(b)'s particularity requirement had been met. *Id.* at 35a. It held that Duxbury met that "flexible" standard because even though the first amended complaint did not identify any specific false claims, it named specific health care providers and included allegations suggesting that OBP's alleged kickbacks had caused those providers to file false claims. *Id.* at 32a-39a.

REASONS FOR GRANTING THE PETITION

This petition raises issues of exceptional importance. Doctors and their patients are well-served when pharmaceutical manufacturers are permitted to speak truthfully about their products. Courts have recognized the public health benefits of permitting the free flow of truthful information about medical products and have recognized broad First Amendment rights both to disseminate and to receive such information. *See, e.g., Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

The free flow of such information is in serious jeopardy, however, as a result of lawsuits such as this one, which seek to impose massive liability on pharmaceutical companies based on their promotional activities. The plaintiffs' bar has filed a torrent of lawsuits seeking to impose FCA liability on those companies based on claims that the promotional activities – which often involve nothing more than speaking truthfully about off-label uses of their products and providing doctors with free samples of those products – are causing others to submit false claims to the federal government. Review is warranted to determine whether Congress really intended to impose FCA liability under these circumstances.

The court below determined that Respondent Duxbury's amended complaint met the heightened pleadings standards of Fed.R.Civ.P. 9(b), despite its failure to identify any specific false claims submitted by a health care practitioner. It did so on the basis of a

"flexible" pleading standard that took into account that relators who do not work for a health care practitioners are highly unlikely to have access to the practitioners' billing records and thus cannot easily obtain information about the submission of specific false claims. As the Petition thoroughly documents, the First Circuit's standard for judging compliance with Rule 9(b)'s "particularity" requirement conflicts sharply with the standards adopted by at least three other federal appeals courts. WLF writes separately to note that the day after the Petition was filed, the Eleventh Circuit issued a decision that rendered the conflict just that much sharper. In a case raising claims virtually identical to those raised by Respondent Duxbury, the Eleventh Circuit affirmed dismissal of the FCA lawsuit against a pharmaceutical manufacturer because the relator failed to identify any specific false claim that was filed as a result of the manufacturer's alleged promotional activities. *Hopper v. Solvay Pharmaceuticals, Inc.*, __ F.3d __, 2009 U.S. App. LEXIS 26381 (Dec. 4, 2009). Review is warranted to resolve the conflict.

Review is also warranted because of the recurring nature of the issue. Virtually every pharmaceutical and medical device company is facing or has faced FCA claims of the type at issue here. Although there is substantial reason to question the validity of many of these suits, the difficulty and expense of defending against FCA claims of this nature mean that defendants – if they cannot prevail on a motion to dismiss – often feel compelled to settle, sometimes for very substantial sums. Clarification of the Rule 9(b) pleading standards in cases of this sort is urgently needed, so that

manufacturers can know how to conform their conduct to the requirements of the FCA. WLF notes, for example, that for valid promotional reasons, pharmaceutical manufacturers annually give away to health care practitioners billions of dollars of free samples of their products. Under the First Circuit's Rule 9(b) standard, allegations that a manufacturer has given away free samples of a drug with the intent that the recipient bill Medicare for the samples are sufficient to withstand a motion to dismiss, notwithstanding the relator's failure to identify a specific false claim submitted for any of the samples. If that is the correct standard, manufacturers may feel compelled to cut back drastically on their use of free samples as a promotional tool.

This case presents a particularly good vehicle for addressing the issue. The outcome of this case unquestionably turns on which Rule 9(b) standard is applied to the amended complaint. Even under the relaxed Rule 9(b) standard it employed, the First Circuit conceded that this case presented a "close call." Because the amended complaint did not specifically identify even one false claim that OBP allegedly caused to be submitted to Medicare officials, there can be little question that the complaint would have been dismissed under the standard adopted by the Sixth, Eighth, and Eleventh Circuits.

Finally, review is warranted because the First Circuit's decision is so clearly at odds with Rule 9(b) and congressional limitations on who may serve as a relator in an FCA suit. Where, as here, the substance of the complaint's allegations was publicly disclosed before

the complaint was filed, the FCA provides that the only proper relators are those who have "direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B). That requirement indicates that Congress expected relators to be able to spell out the alleged fraud with the "particularity" demanded by Rule 9(b) – including information about specific false claims submitted to the federal government for payment. By applying a relaxed Rule 9(b) standard that excused Respondent Duxbury's failure to specifically identify *any* false claim, the First Circuit ignored § 3730(e)(4)(B). It is difficult to comprehend how a relator could be deemed to have "direct and independent knowledge" regarding false claims when he cannot identify even one such claim with "particularity."

I. THE DECISION BELOW CONFLICTS WITH RULE 9(b) STANDARDS ADOPTED BY AT LEAST THREE OTHER CIRCUITS, AND A POST-PETITION DECISION INTENSIFIES THE CONFLICT

The Petition explains in detail the direct conflict between the Rule 9(b) standard laid down by the First Circuit's decision and the standards adopted by the Sixth, Eighth, and Eleventh Circuits. Pet. 24-31 (citing *Yuhasz v. Brush-Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552 (8th Cir. 2006); *United States ex rel. Clausen v. Laboratory Corp. of America*, 290 F.3d 1301 (11th Cir. 2002). *See also United States ex rel. Marlar v. BYXT Y-12, L.L.C.*, 525 F.3d 439, 444-45 (6th Cir. 2008) ("Where the complaint alleges a complex and

far-reaching fraudulent scheme, then that scheme must be pleaded with particularity and the complaint must also provide examples of specific fraudulent conduct."). WLF will not repeat the Petition's cogent explanation; WLF agrees that review is warranted to resolve the conflict among the federal appeals courts identified by the Petition.

WLF writes separately to call attention to an Eleventh Circuit decision issued the day after the Petition was filed; the decision renders the conflict just that much sharper. In a case raising claims virtually identical to those raised by Respondent Duxbury, the Eleventh Circuit affirmed dismissal of an FCA lawsuit against a pharmaceutical manufacturer because the relator failed to identify any specific false claim that was filed as a result of the manufacturer's alleged promotional activities. *Hopper v. Solvay Pharmaceuticals, Inc.*, __ F.3d __, 2009 U.S. App. LEXIS 26381 (Dec. 4, 2009).

The *qui tam* relator in *Hopper* alleged that a pharmaceutical company caused health care providers to submit false claims for reimbursement to government-run health care programs by: (1) promoting widespread off-label use of the company's drug; and (2) giving kickbacks to health care providers to induce them to write prescriptions for the drug. 2009 U.S. App. LEXIS 26381 at *6. The Eleventh Circuit acknowledged that the complaint offered "detailed allegations of an illegal scheme to cause the government to pay amounts it did not owe" and a "highly compelling statistical analysis that renders inescapable the conclusion that a huge number of claims for ineffective off-label uses of" the

drug were submitted to the federal government for payment. *Id.* at *14. The appeals court nonetheless upheld dismissal of the complaint for failure to meet Rule 9(b)'s "particularity" requirement:

> Rule 9(b) requires that actual presentment of a claim be pled with particularity. Because the relators' complaint fails to assert the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government, the district court did not err by concluding that the complaint failed to plead fraud with particularity.

Id. at *17-*18 (citations omitted).

The Rule 9(b) standard adopted in *Hopper* directly conflicts with the Rule 9(b) standard adopted in this case. The First Circuit held that when an FCA relator does not allege that the defendant itself submitted false claims but rather induced others to submit false claims, a "more flexible" Rule 9(b) standard is applicable and the complaint need not specifically identify any false claims submitted to the government. Pet. App. 32a-35a. In contrast, although *Hopper* (as here) involved a claim that the defendant caused *others* to submit false claims, the Eleventh Circuit applied the same strict Rule 9(b) standard it had previously applied to cases in which the defendant itself was alleged to have submitted the false claims. Dismissal of the complaint was upheld in the absence of allegations regarding the who, what, where, when, and how of fraudulent submissions to the government. *Hopper* at *17-*18.

The amended complaint filed by Respondent Duxbury met only the "who" component: it stated the names of several health care providers alleged to have been induced by OBP to submit false claims. Amended Compl. ¶ 211, Pet. App. 96a-101a. But he has not supplied answers to the what, where, when, and how components. Not for even a single "false claim" are details provided regarding the date on which the claim was submitted, how it was submitted, how much money was sought, and how much money was paid. The First Circuit held that the amended complaint met Rule 9(b)'s particularity requirement; *Hopper* indicates that the Eleventh Circuit would have reached the opposite conclusion. Review is warranted to resolve the direct conflict between the First and Eleventh Circuits.[3]

II. REVIEW IS WARRANTED IN LIGHT OF THE IMPORTANCE OF THE QUESTION PRESENTED AND ITS RECURRING NATURE

Review is also warranted in light of the importance to health care delivery of the issues raised by the petition. Virtually every pharmaceutical and

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[3] The Eleventh Circuit's *Hopper* decision included a brief discussion of the First Circuit's decision in this case. The Eleventh Circuit explained that *Duxbury* was distinguishable with regard to one factual issue: in contrast to the defendant in *Hopper*, Respondent Duxbury had alleged facts sufficient to give rise to an inference that OBP had intended to cause the submission of false claims. *Hopper*, at *29-*30. But that statement does nothing to lessen the conflict between the First and Eleventh Circuits on the central issue: the degree of "particularity" required by Rule 9(b) in alleging the submission and payment of actual false claims.

medical device company is facing or has faced FCA claims of the type at issue here. Moreover, there is no reason to delay review of the issue; the conflict among the federal appeals courts is already pronounced and shows no sign of abating on its own.

Coming up with a precise tally of the number of improper-promotion FCA lawsuits filed in recent years against pharmaceutical companies is a difficult task in light of confidentiality provisions embedded in the FCA. Any FCA lawsuit filed by a private relator must be filed in camera and remains under seal until the federal government has sufficient time (usually, well in excess of a year) to determine whether it will intervene in the action and conduct the action in its own name. *See* 31 U.S.C. § 3730(b). Nonetheless, press accounts confirm that there has been a torrent of such suits in which the promotional activities of pharmaceutical companies are alleged to have induced others to file false claims with Medicare and Medicaid officials. *See, e.g.*, Richard C. Ausness, *"There's Danger Here, Cherie!" Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses*, 73 BROOKLYN L. REV. 1253 (2008). Prominent FCA cases of this nature that have led to reported, substantive decisions include (in addition to this case and *Hopper*): *United States ex rel. Rost v. Pfizer*, 507 F.3d 720 (1st Cir. 2007); *United States ex rel. Hess v. Sanofi-Synthelabo*, No. 05-570, 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006); and *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001). In every one of these case, the central issue was whether the relator had alleged the submission of false claims with sufficient "particularity" to satisfy Rule 9(b)'s heightened pleadings standards.

In numerous other instances, pharmaceutical companies have decided to settle FCA claims (often for substantial sums) rather than incurring the massive costs of defending such suits and risking the possibility that an unfavorable decision could result in imposition of ruinous liability. Recent settlements of FCA suits filed by relators have included $800 million paid by Eli Lilly & Co. in January 2009 (marketing of Zyprexa); $671 million paid by Merck & Co. in February 2008 (alleged kickbacks to doctors); $668 million paid by Pfizer in October 2009, plus another $331 million under state FCA laws (off-label marketing practices); $515 million paid by Bristol-Myers Squibb in September 2007 (alleged kickbacks and off-label promotion); $425 million paid by Cephalon in November 2007 (marketing of Actiq, Provigil, and Gabitril); $400 million paid by Abbott Laboratories in July 2003 (marketing of "enteral" products); $311 million paid in September 2007 by four manufacturers of hip and knee surgical implant products (payment of consulting fees to surgeons); and $266 million paid by AstraZeneca Pharmaceuticals in June 2003 (marketing of Zoladex). *See generally,* U.S. Dep't of Justice, "More Than $1 Billion Recovered by Justice Department in Fraud and False Claims in Fiscal Year 2008" (Nov. 10, 2008), *available at* www.justice.gov/opa/pr/2008/November/08-civ-992.html.

WLF does not mean to suggest that there was no merit in any of the settled FCA cases filed against pharmaceutical companies based on their alleged improper marketing. Indeed, most of the cases involving large settlements were ones in which the federal government investigated the private relators'

claims and found those claims sufficiently meritorious that it decided to intervene. Rather, we cite the above cases simply as evidence that FCA lawsuits challenging the marketing practices of pharmaceutical companies are a widespread and growing phenomenon. In all such cases – particular where, as here, the federal government has investigated the allegations and has declined to intervene – a threshold issue is whether a health care provider has actually been induced by the defendants' promotional activities to file a false claim.[4] Thus, the Rule 9(b) issue is of critical importance. If an FCA relator can survive a motion to dismiss despite failing to specifically identify a single false claim submitted to Medicare or Medicaid officials, then numerous pharmaceutical companies can be expected to settle even non-meritorious FCA suits rather than incur the costs of discovery.[5]

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[4] Although Rule 9(b) prevents a private relator from engaging in fishing expeditions in an effort to establish his FCA claims, the federal government is not similarly constrained. Even before filing suit, the Attorney General is empowered to demand the production of all documents and testimony relevant to an investigation into possible FCA violations. *See* 31 U.S.C. § 3733(a).

[5] There is considerable reason to doubt the merit of many of the current wave of FCA suits. For example, many of the suits hinge on a claim that payments/discounts offered by a drug manufacturer to health care practitioners are improper unless explicitly reflected in the manufacturer's Average Wholesale Price (AWP), and thus that all requests for reimbursement on the basis of AWP constitute "false claims." A recent decision by the Alabama Supreme Court calls that theory into question; the court noted that federal and state Medicaid/Medicare officials are well aware that AWP does *not* reflect any discounts. *AstraZeneca LP v. State of Alabama*, 2009 Ala. LEXIS 244 (Ala., Oct. 16, 2009) (overturning several hundred million dollars in common law fraud judgments

Clarification of the Rule 9(b) pleading standards is particularly important in cases of this sort, so that manufacturers can know how to adjust their marketing techniques in order to minimize the number of private FCA lawsuits they are likely to face. WLF notes, for example, that for valid promotional reasons, pharmaceutical manufacturers annually give away to health care practitioners billions of dollars of free samples of their products. *See, e.g.*, Andrew Zajac, "A Prescription for Snooping," *Los Angeles Time* (Dec. 14, 2009) at E1 (the retail value of free samples provided in the U.S. by pharmaceutical companies in 2004 was $15.9 billion, according to a Kaiser Family Foundation study). Under the First Circuit's Rule 9(b) standard, allegations that a manufacturer has given away free samples of a drug with the intent that the recipient bill Medicare for the samples are sufficient to withstand a motion to dismiss, notwithstanding the relator's failure to identify a specific false claim submitted for any of the samples. If that is the correct standard, manufacturers may feel compelled to cut back drastically on their use of free samples as a promotional tool.

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against three pharmaceutical manufacturers).

WLF is similarly skeptical of Duxbury's claim that OBP's management provided free samples to health care providers with the understanding that the providers would seek "reimbursement" from Medicare for the supposed cost of those samples. It is a serious violation of the FDCA for anyone to sell or offer to sell any drug sample. *See* 21 U.S.C. § 353(c)(1). Drug manufacturers have so many legitimate promotional reasons for wanting to distribute drug samples that it is difficult to believe that they would choose to use the distribution process for the additional purpose of aiding and abetting crimes by health care providers, particularly when manufacturers do not stand to gain financially from the crime.

This case presents a particularly good vehicle for addressing the issue. The outcome of this case unquestionably turns on which Rule 9(b) standard is applied to the amended complaint. Even under the relaxed Rule 9(b) standard it employed, the First Circuit conceded that this case presented a "close call." Because the amended complaint did not specifically identify even one false claim that OBP allegedly caused to be submitted to Medicare officials, there can be little question that the complaint would have been dismissed under the standard adopted by the Sixth, Eighth, and Eleventh Circuits. Moreover, if review is denied, OBP will have lost all opportunity for review of the Rule 9(b) issue. Denial of review may well, of course, force OBP to settle as a less expensive alternative to enduring discovery. But even if the case is litigated to judgment, appellate review will turn on the evidence presented at trial, not on the adequacy of allegations contained in the initial complaint.

In sum, review is warranted in light of the importance of the issues raised, their recurring nature, and the inability to obtain review of the question presented at any later stage of the case.

III. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW IS INCONSISTENT WITH LIMITATIONS IMPOSED BY CONGRESS ON PRIVATE FCA SUITS

Review is also warranted because the First Circuit's decision is so clearly at odds with Rule 9(b) and congressional limitations on who may serve as a relator in an FCA suit.

The history of the FCA evidences Congress's attempt to balance the encouragement of true whistleblower activity and the discouragement of opportunistic behavior. Congress established the public disclosure bar in 1986 for the purpose of preventing parasitic lawsuits by *qui tam* relators bringing suits based on information that has already been disclosed and thus is readily available to government investigators. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007). When, as here, the information contained in an FCA complaint was publicly disclosed before the complaint was filed, the suit is jurisdictionally barred unless the relator qualifies as an "original source" of the information. 31 U.S.C. § 3730(e)(4)(A). An individual is an "original source" if, *inter alia*, he has "direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B). Thus, Duxbury's right to maintain this action hinges on his assertion that he has "direct and independent knowledge of the information" on which his allegations against OBP are based.

Even today, seven years after filing his lawsuit, Duxbury plainly does know all the information on which his allegations against OBP are based. He concedes that he is unaware of the details of even a single false claim submitted to and/or paid by the federal government as a result of OBP's alleged misconduct. *See* Amended Compl. ¶ 232, Pet. App. 102a. Yet, the First Circuit excused that lack of knowledge, reasoning that Rule 9(b)'s "particularity" requirement does not require the pleading of such information – at least where, as here, the FCA suit is based on an allegation that the defendant did not file its own false claims but rather

caused others to do so. *Id.* at 32a-35.

That conclusion is plainly at odds with Congress's intent in establishing the public disclosure bar and the "original source" exception thereto. When it adopted the requirement that an "original source" have "direct and independent knowledge of the information on which the allegations are based," 31 U.S.C. § 3730(e)(4)(B), Congress expressed its expectation that relators would to be able to spell out the alleged fraud with the "particularity" demanded by Rule 9(b) – including information about specific false claims submitted to the federal government for payment. By applying a relaxed Rule 9(b) standard that excused Respondent Duxbury's failure to specifically identify *any* false claim, the First Circuit ignored § 3730(e)(4)(B). It is difficult to comprehend how a relator could be deemed to have "direct and independent knowledge" regarding false claims when he cannot identify even one such claim with "particularity."

The First Circuit's decision to excuse Respondent Duxbury's lack of knowledge appears to be based on a "sporting chance" theory of litigation. It would not be fair to dismiss FCA suits filed by relators situated as was Duxbury, the First Circuit apparently reasoned, because otherwise such relators would never be able to avoid dismissal of their FCA suits – since employees of pharmaceutical companies are unlikely to have inside knowledge of the billing practices of health care providers to whom the pharmaceutical companies sell their products. But Congress did not establish the *qui tam* provision to give every relator a sporting chance of winning his lawsuit. Rather, the *qui tam* provision was

adopted to allow the government to "purchase" from private individuals the information they may have about fraud on the United States Treasury. *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 309 (5th Cir. 1999). Because Duxbury does not have any information demonstrating that the Treasury was actually defrauded (but rather has simply made an educated guess that fraud occurred), § 3730(e)(4)(B) makes clear that Congress did not intend to permit Duxbury to seek a cash bounty by using the discovery process in an attempt to uncover actual evidence of fraud.

Review is warranted to correct the First Circuit's clear misinterpretation of the Rule 9(b) "particularity" requirement.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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